

University of Dundee

Decision aids for people facing health treatment or screening decisions (Review)

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[Intervention Review]

Decision aids for people facing health treatment or screening decisions

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ABSTRACT

Background

Decision aids prepare people to participate in 'close call' decisions that involve weighing benefits, harms, and scientific uncertainty.

Objectives

To conduct a systematic review of randomised controlled trials (RCTs) evaluating the efficacy of decision aids for people facing difficult treatment or screening decisions.

Search strategy

We searched MEDLINE (Ovid) (1966 to July 2006); Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*; 2006, Issue 2); CINAHL (Ovid) (1982 to July 2006); EMBASE (Ovid) (1980 to July 2006); and PsycINFO (Ovid) (1806 to July 2006). We contacted researchers active in the field up to December 2006. There were no language restrictions.

Selection criteria

We included published RCTs of interventions designed to aid patients' decision making by providing information about treatment or screening options and their associated outcomes, compared to no intervention, usual care, and alternate interventions. We excluded studies in which participants were not making an active treatment or screening decision, or if the study's intervention was not available to determine that it met the minimum criteria to qualify as a patient decision aid.

Data collection and analysis

Two review authors independently screened abstracts for inclusion, and extracted data from included studies using standardized forms. The primary outcomes focused on the effectiveness criteria of the International Patient Decision Aid Standards (IPDAS) Collaboration: attributes of the decision and attributes of the decision process. We considered other behavioural, health, and health system effects as secondary outcomes. We pooled results of RCTs using mean differences (MD) and relative risks (RR) using a random effects model.

Main results

This update added 25 new RCTs, bringing the total to 55. Thirty-eight (69%) used at least one measure that mapped onto an IPDAS effectiveness criterion: decision attributes: knowledge scores (27 trials); accurate risk perceptions (11 trials); and value congruence with chosen option (4 trials); and decision process attributes: feeling informed (15 trials) and feeling clear about values (13 trials).

This review confirmed the following findings from the previous (2003) review. Decision aids performed better than usual care interventions in terms of: a) greater knowledge (MD 15.2 out of 100; 95% CI 11.7 to 18.7); b) lower decisional conflict related to feeling uninformed (MD -8.3 out of 100; 95% CI -11.9 to -4.8); c) lower decisional conflict related to feeling unclear about personal values (MD -6.4; 95% CI -10.0 to -2.7); d) reduced the proportion of people who were passive in decision making (RR 0.6; 95% CI 0.5 to 0.8); and e) reduced proportion of people who remained undecided post-intervention (RR 0.5; 95% CI 0.3 to 0.8). When simpler decision aids were compared to more detailed decision aids, the relative improvement was significant in knowledge (MD 4.6 out of 100; 95% CI 3.0 to 6.2) and there was some evidence of greater agreement between values and choice.

In this review, we were able to explore the use of probabilities in decision aids. Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions (RR 1.6; 95% CI 1.4 to 1.9). The effect was stronger when probabilities were measured quantitatively (RR 1.8; 95% CI 1.4 to 2.3) versus qualitatively (RR 1.3; 95% CI 1.1 to 1.5).

As in the previous review, exposure to decision aids continued to demonstrate reduced rates of: elective invasive surgery in favour of conservative options, decision aid versus usual care (RR 0.8; 95% CI 0.6 to 0.9); and use of menopausal hormones, detailed versus simple aid (RR 0.7; 95% CI 0.6 to 1.0). There is now evidence that exposure to decision aids results in reduced PSA screening, decision aid versus usual care (RR 0.8; 95% CI 0.7 to 1.0). For other decisions, the effect on decisions remains variable.

As in the previous review, decision aids are no better than comparisons in affecting satisfaction with decision making, anxiety, and health outcomes. The effects of decision aids on other outcomes (patient-practitioner communication, consultation length, continuance, resource use) were inconclusive.

There were no trials evaluating the IPDAS decision process criteria relating to helping patients to recognize a decision needs to be made, understand that values affect the decision, or discuss values with the practitioner.

Authors' conclusions

Patient decision aids increase people's involvement and are more likely to lead to informed values-based decisions; however, the size of the effect varies across studies. Decision aids have a variable effect on decisions. They reduce the use of discretionary surgery without apparent adverse effects on health outcomes or satisfaction. The degree of detail patient decision aids require for positive effects on decision quality should be explored. The effects on continuance with chosen option, patient-practitioner communication, consultation length, and cost-effectiveness need further evaluation.

PLAIN LANGUAGE SUMMARY

Decision aids to help people who are facing health treatment or screening decisions

Making a decision about the best option to manage health can be difficult. Getting information on the options and the possible benefits and harms in the form of decision aids may help. Decision aids, such as pamphlets and videos that describe options, are designed to help people understand the options, consider the personal importance of possible benefits and harms, and participate in decision making. They are used when there is more than one medically reasonable option - no option has a clear advantage in terms of health outcomes, each has benefits and harms that people value differently. The updated review of trials found that decision aids improve people's knowledge of the options, create accurate risk perceptions of their benefits and harms, reduce difficulty with decision making, and increase participation in the process. They may have a role in preventing use of options that informed patients don't value without adversely affecting health outcomes. They did not seem to have an effect on satisfaction with decision making or anxiety.

BACKGROUND

Many health treatment and screening decisions have no single 'best' choice. These types of decisions are considered 'close calls' because there is scientific uncertainty about outcomes or there is a need to trade off known benefits and harms. In 2005, Clinical Evidence classified 47% of treatments as having insufficient evidence and 8% of its treatments as 'tradeoffs between benefits and harms' (Godlee 2005).

To prepare people to discuss close call decisions with their practitioner, patient decision aids have been developed (Deber 1994a; Deber 1994b; Gafni 1998 Deber 1994a; Deber 1994b; Martin 2002; RTI 1997). Decision aids differ from usual health education materials because of their detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making. In contrast, health education materials are broader in perspective, helping people to understand their diagnosis, treatment, and management in general terms, but not necessarily helping them to participate in decision making.

According to the International Patient Decision Aids Standards (IPDAS) Collaboration (Elwyn 2006; IPDAS 2005a; Elwyn 2006), patient decision aids are evidence-based tools designed to prepare clients to participate in making specific and deliberated choices among healthcare options in ways they prefer. Patient decision aids supplement (rather than replace) clinician's counselling about options. The specific aims of decision aids and the type of decision support they provide may vary slightly, but in general they:

1. provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties;
2. help patients to recognize the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value they place on the benefits, harms, and scientific uncertainties. Strategies that may be included in the decision aid are: describing the options in enough detail that clients can imagine what it is like to experience the physical, emotional, and social effects; and guiding clients to consider which benefits and harms are most important to them; and
3. provide structured guidance in the steps of decision making and communication of their informed values with others involved in the decision (e.g. clinician, family, friends).

Decision aids can be used before, during, or after the clinical encounter to enable patients to become active, informed participants.

Decision aids are being developed in several centres, primarily in North America, Europe, and Australia. Since 1999, there has been a rapid proliferation of patient decision aids; in 2006, decision aids from large scale producers were accessed over 8 million times (O'Connor 2007). In response to concerns about variability in quality of patient decision aids, the IPDAS Collaboration reached

agreement on criteria for judging their quality (Elwyn 2006). More than 100 researchers, practitioners, patients, and policy makers from 14 countries participated. Participants addressed three domains of quality: clinical content, development process, and evaluation of a patient decision aid's effectiveness.

The ultimate goal of patient decision aids is to improve decision making. Over the past decade, there has been considerable debate about the definition of a 'good decision', when there is no single 'best' therapeutic action and choices depend on how patients value benefits versus harms (Briss 2004; O'Connor 2003a; O'Connor 1997b; Ratliff 1999; Sepucha 2004). IPDAS reached agreement on criteria for judging "the things that you would need to observe in order to say that after using a patient decision aid, the way the decision was made was good, and that the choice that was made was good" (Elwyn 2006; IPDAS 2005b). The criteria were as follows:

- Decision: There is evidence that the patient decision aid improves the match between the chosen option and the features that matter most to the informed patient.
- Decision process: There is evidence that the patient decision aid helps patients to: recognize that a decision needs to be made; know options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in preferred ways.

Several individual trials examining the efficacy of decision aids have been published. There are annotated bibliographies, reports, and general reviews of decision aids (Bekker 1999; Bekker 2003; RTI 1997 Estabrooks 2000; Molenaar 2000; O'Connor 1997a; O'Connor 1999c; RTI 1997; Whelan 2002; Bekker 2003). We published the first systematic review of 17 randomised trials of decision aids in 1999 (O'Connor 1999b), followed by an update on 35 trials in 2003 (O'Connor 2003b).

OBJECTIVES

To conduct a systematic review of randomised controlled trials evaluating the efficacy of decision aids for people facing difficult treatment or screening decisions.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published studies using a randomised controlled trial (RCT) design comparing decision aids to no intervention, usual care, alternative interventions, or a combination.

Types of participants

We included studies involving people who were making decisions about screening or treatment options for themselves, for a child, or for an incapacitated significant other. We excluded studies in which participants were making hypothetical choices.

Types of interventions

Decision aids were defined as interventions designed to help people make specific and deliberative choices among options (including the status quo) by providing (at the minimum) information on the options and outcomes relevant to a person's health status and implicit methods to clarify values. The aid also may have included: information on the disease/condition; costs associated with options; probabilities of outcomes tailored to personal health risk factors; an explicit values clarification exercise; information on others' opinions; a personalized recommendation on the basis of clinical characteristics and expressed preferences; and guidance or coaching in the steps of decision making and in communicating with others.

We excluded studies if interventions focused on: decisions about lifestyle changes, clinical trial entry, or general advance directives (e.g. do not resuscitate); education programs not geared to a specific decision; and interventions designed to promote adherence to or to elicit informed consent regarding a recommended option. We also excluded studies whose interventions were not available to determine that they provided the minimum criteria to qualify as a patient decision aid.

Types of outcome measures

Evaluation of outcomes depends on the framework used to develop the decision aids (RTI 1997 Charles 1997; Entwistle 1998; Llewellyn-Thomas'95; Makoul 2006; Mulley 1995; O'Connor 1998b; Rothert 1987; RTI 1997; Ruland 2002; Stacey 2007; Whitney 2003). To ascertain whether the decision aids achieved their objectives, we examined a broad range of **positive or negative** effects. Although the decision aids focused on diverse clinical decisions, many had similar objectives such as improving knowledge, accurate risk perceptions and participation in decision making. Many of these evaluation criteria mapped onto the IPDAS criteria for evaluating the effectiveness of decision aids. A total list of outcomes, specified in advance of the review, included:

Primary outcomes

Evaluation criteria which map onto the IPDAS criteria

- Attributes of the decision: There is evidence that the patient decision aid improves the match between the chosen option and the features that matter most to the informed patient (including outcomes such as knowledge, accurate risk perceptions, and value congruence with chosen option).

- Attributes of the decision process: There is evidence that the patient decision aid helps patients to: recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in preferred ways.

Other decision making process variables

- Decisional conflict.
- Patient-practitioner communication.
- Participation in decision making.
- Satisfaction.

Secondary outcomes

Behaviour

- Decisions (proportion undecided, option selected).
- Adherence to chosen option.

Health outcomes

- Health status and quality of life (generic and condition-specific).
- Anxiety, depression, emotional distress, regret, confidence.

Healthcare system

- Patients' and physicians' satisfaction.
- Costs, cost effectiveness.
- Consultation length.
- Litigation rates.

Search methods for identification of studies

Our search strategy for the review included:

1. searching electronic medical and social science databases; and
2. contacting known developers and evaluators through a shared decision making list-serve and e-mail contacts up to December 2006.

We searched the following electronic databases: MEDLINE (Ovid) (1966 to July 2006); Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library*; 2006, Issue 2);

CINAHL (Ovid) (1982 to July 2006); EMBASE (Ovid) (1980 to July 2006); and PsycINFO (Ovid) (1806 to July 2006). We present the search strategies in [Appendices](#).

Data collection and analysis

This update differed from our previous Cochrane reviews ([O'Connor 2001b](#); [O'Connor 2003b](#)) by focusing on the new IPDAS criteria. Moreover, we used new systematic review software, TrialStat SRS, to manage the search and data extraction; therefore our search, screen and data collection procedures were redone completely. Two review authors (CB, SK, DS, AO, or VF) screened all reports of RCTs and extracted data independently using TrialStat SRS 3.0 software. No review author screened or extracted data from any of their own studies. We resolved inconsistencies by discussion and consensus. Wherever possible, we obtained missing data from the authors. Risk of bias was assessed by two review authors independently (CB, SK, DS, AO, or VF) using the Jadad scale ([Jadad 1996](#)) plus the criterion of allocation concealment.

We described study results individually. There were planned comparisons between groups receiving: a) usual care versus decision aids; and b) simpler versus detailed decision aids. For studies in which there was more than one intervention group and one control group, we extracted data from the two groups that provided the strongest contrast. For example, the group that used the most detailed decision aid was compared with those who used the least detailed decision aid, or received usual care.

We pooled results across studies in cases where: a) similar outcome measures were used; and b) the effects were expected to be independent of the type of decision studied. For example, decision aids were expected to improve knowledge of options, benefits and harms; to create realistic expectations of benefits/harms; to reduce decisional conflict; and to enhance active participation in decision making. Therefore, we pooled data from the RCTs for these outcomes, if comparable measures were used. When analysing the effects of decision aids on choices, we pooled outcomes on more homogenous subgroups of decisions (preference for major surgery versus conservative options; PSA testing or not; menopause hormone therapy or not; etc.). In addition, we analysed studies comparing usual care to decision aids separately from studies comparing simple to more detailed decision aids.

We used Review Manager 4.2 (2003) to estimate a weighted treatment effect (with 95% confidence intervals). For continuous measures, we used mean differences (MD); for dichotomous outcomes, we calculated pooled relative risks (RR). We analysed all data with a random effects model because of the diverse nature of the studies being combined.

Due to statistically significant heterogeneity for most of the outcomes, we performed post hoc sub-analyses to explore potential sources of heterogeneity. Focusing on the IPDAS effectiveness criteria, we explored heterogeneity according to the following factors: type of decision (treatment versus screening), type of media

of the decision aid (video/computer versus audio booklet/pamphlet), and possibility of a ceiling effect based on usual-care scores (removal of studies with lower knowledge and realistic perceptions scores; removal of studies with higher decisional conflict scores for subscales feeling uninformed and unclear values). We analysed the effect of removing the biggest outlier(s) (defined by visual inspection of forest plots). Additionally, we performed a post hoc analysis to examine the effect of excluding trials of lower methodological quality, and excluding trials that were outliers and contributing to heterogeneity.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of ongoing studies](#).

Results of the search

We identified 22,778 unique citations from the electronic database searches. Of these, only 1,293 citations focused on people's decision making.

Of the 1,293 citations identified, 130 appeared to be evaluations of interventions. We excluded 64 of these. Sixty-four were excluded upon close perusal of the paper. The reasons for exclusion were: a) the study was not focused on making a choice ($n = 33$); b) the study was not a randomised controlled trial ($n = 14$); c) the intervention offered no decision support in the form of a decision aid ($n = 8$); d) the decision was hypothetical with participants not actually at a point of decision making ($n = 6$); e) no outcome data were provided ($n = 2$); and protocol only ($n = 1$).

We identified 15 ongoing RCTs (1 through the database search and 14 through personal contact) (see references to Ongoing studies, and table [Characteristics of ongoing studies](#)).

Included studies

The remaining 66 citations provided data on 55 trials which met our inclusion criteria. The 55 RCTs, presenting results from seven countries (Australia, Canada, China, Finland, Netherlands, United States, and the United Kingdom), evaluated 23 different screening or treatment decisions.

The current version of our review updates our 2003 version ([O'Connor 2003b](#), which included 34 efficacy trials) with 25 new trials ([Auvinen 2004](#); [Bekker 2004](#); [Deschamps 2004](#); [Frosch 2003](#); [Gattellari 2003](#); [Gattellari 2005](#); [Green 2004](#); [Hunter 2005](#); [Johnson 2006](#); [Lalonde 2006](#); [Laupacis 2006](#); [Legare 2003](#); [Leung 2004](#); [McAlister 2005](#); [Miller 2005](#); [Montgomery 2003](#); [Myers 2005a](#); [Oakley 2006](#); [Partin 2004](#); [Shorten 2005](#); [vanRoosmalen](#)

2004; Vuorma 2003; Whelan 2003; Whelan 2004; Wong 2006). Four trials (Davison 1999; Maisels 1983; Michie 1997; Thornton 1995) that were included in the 2003 review were excluded from this update, as the decision support intervention was not available to determine whether it met the inclusion criteria - a requirement for this update of the new IPDAS standards.

Unit of randomisation

All but four trials randomised individual patients. Goel 2001 randomised 57 surgeons; Legare 2003 randomised 40 family physicians; Whelan 2004 randomised 27 surgeons; and McAlister 2005 randomised 102 primary care practices. For two studies (Goel 2001; Whelan 2004) the cluster effect was taken into account in the published outcome data and the meta-analysis used published results. For McAlister 2005, meta-analysis was done applying the design effect (based on the published intracluster correlation coefficient (ICC)). For Legare 2003 the authors stated that for the Decisional Conflict Scale results "Clustering had no impact on individual scores of women and therefore, we present the results without adjustment". We were unable to obtain an ICC from the authors so we conducted sensitivity analyses, varying the ICC from 0.02 to a conservative 0.2 to calculate a design effect. There was no substantial change in pooled estimate, so we have chosen to present the outcome data as published.

Decision aids and comparisons

The 55 included RCTs evaluated 51 separate decision aids (Additional Table 1). The decision aids used a variety of formats and were compared to a variety of control interventions. We noted the nature of usual care when reported. We describe briefly below the types of decisions covered and comparisons that were made in the included studies.

Table 1. Decision aids evaluated in the RCTs

Study	Topic	Availability	Source	Contact Information
Auvinen 2004	Prostate cancer treatment	Yes	Auvinen, Helsinki, Finland, 1993	included in publication
Barry 1997	Benign prostate disease treatment	Yes	Foundation for Informed Medical Decision Making (FIMDM), Hanover NH, US, 2001	www.healthdialog.com
Bekker 2004	Prenatal screening	Yes	Bekker, Leeds, UK, 2003	included in publication
Bernstein 1998	Ischaemic heart disease treatment	Yes	FIMDM, Hanover NH, US, 2002	www.healthdialog.com
Clancy 1988	Hepatitis B Vaccine	No	Clancy, Richmond VA, US, 1983	

Table 1. Decision aids evaluated in the RCTs (Continued)

Davison 1997	Prostate cancer treatment	No	Davison, Manitoba CA, 1992-1996	
Deschamps 2004	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	
Deyo 2000	Back surgery	Yes	FIMDM, Hanover NH, US, 2001	www.healthdialog.com
Dodin 2001	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	
Dolan 2002	Colon cancer screening	No	Dolan, Rochester NY, US, 1999	
Dunn 1998	Infant vaccination schedule	No	Dunn, East Lansing MI, US, 1998	
Frosch 2003	Prostate cancer screening	Yes	FIMDM, Hanover NH, 1999	www.healthdialog.com
Gattellari 2003	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication
Gattellari 2005	Prostate cancer screening	Yes	Gatellari, Sydney, AU, 2003	included in publication
Goel 2001	Breast cancer surgery	Yes	Goel/Sawka, Toronto CAN, 2001	www.breastcancersurgery.cancer.ca
Green 2001a	Breast cancer genetic testing	Yes	Green, Hershey PA, US, 2000	1-800-757-4868 dwc@mavc.com
Green 2004	Breast cancer genetic testing	Yes	Green, Hershey PA, US, 2000	1-800-757-4868 dwc@mavc.com
Herrera 1983	Infant male circumcision	No	Herrera, Baltimore MD, US, 1983	
Hunter 2005	Prenatal screening	No	Hunter, Ottawa, CA, 2000	
Johnson 2006	Endodontic treatment	Yes	Johnson, Chicago, US, 2004	Included in publication
Kennedy 2002	Abnormal uterine bleeding treatment	No	Kennedy/Coulter, London UK, 1996	

Table 1. Decision aids evaluated in the RCTs (Continued)

Lalonde 2006	Cardiovascular health treatment	Yes	Lalonde, Ottawa, CA, 2002	www.decisionaid.ohri.ca
Laupacis 2006	Pre-operative autologous blood donation	Yes	Laupacis, Ottawa, CA, 2001	www.decisionaid.ohri.ca
Legare 2003	Hormone replacement therapy	No	O'Connor, Ottawa, CA, 1996	
Lerman 1997	Breast cancer genetic testing	No	Lerman/Schwartz, Washington DC, US, 1997	
Leung 2004	Prenatal screening	No	Leung, Hong Kong, China, 2001	
Man-Son-Hing 1999	Atrial fibrillation treatment	Yes	McAlister/Laupacis, Ottawa CAN, 2000	www.decisionaid.ohri.ca
McAlister 2005	Atrial fibrillation treatment	Yes	McAlister/Laupacis, Ottawa CAN, 2000	www.decisionaid.ohri.ca
McBride 2002	Hormone replacement therapy	Yes, update in progress	Sigler/Bastien, Durham NC, US, 1998	basti001@mc.duke.edu
Miller 2005	BRCA1 BRCA2 gene testing	No	Miller, Fox Chase PA, US	
Montgomery 2003	Hypertension treatment	Yes	Montgomery, UK, 2000	Included in publication
Morgan 2000	Ischaemic heart disease treatment	Yes	FIMDM, Hanover NH, US, 2002	www.healthdialog.com
Murray 2001a	Benign prostate disease treatment	Yes	FIMDM, Hanover NH, US, 2001	www.healthdialog.com
Murray 2001b	Hormone replacement therapy	No, update in progress	FIMDM, Hanover NH, US,	www.healthdialog.com
Myers 2005a	Prostate cancer screening	Yes	Myers, Philadelphia PA, US, 1999	Included in publication
O'Connor 1998a	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	
O'Connor 1999a	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	

Table 1. Decision aids evaluated in the RCTs (Continued)

Oakley 2006	Osteoporosis treatment	Yes	Cranney, Ottawa CA, 2002	www.decisionaid.ohri.ca
Partin 2004	Prostate cancer screening	Yes	FIMDM, Hanover NH, US, 2001	www.healthdialog.com
Phillips 1995	Dental orthognathic surgery	Yes, commercial	Phillips, Chapel Hill NC, US, 1995	Ceib·Phillips@DENTISTRY.UNC.EDU
Pignone 2000	Colon cancer screening	Yes	Pignone, Chapel Hill NC, US, 1999	www.med.unc.edu/medicine/edusrc/colon.htm
Rostom 2002	Hormone replacement therapy	No	O'Connor, Ottawa CA, 1996	
Rothert 1997	Hormone replacement therapy	No, update in progress	Rothert, East Lansing MI, US, 1999	
Schapira 2000	Prostate specific antigen testing	Yes	Schapira, Milwaukee WI, US, 1995	mschap@mcw.edu
Schwartz 2001	Breast cancer genetic testing	No	Schwartz/Lerman, Washington DC, US, 1997	
Shorten 2005	Birthing options after previous caesarean	Yes (updated 2006)	Shorten, Wollongong, AU, 2000	
Street 1995	Breast cancer surgery	No	Street, College Station TX, US, 1995	
vanRoosmalen 2004	BRCA1/2 mutation: prophylactic surgery	Yes	vanRoosmalen, Netherlands, 1999	see publication
Volk 1999	Prostate specific antigen testing	Yes	FIMDM, Hanover NH, US, 1999	www.healthdialog.com
Vuorma 2003	Menorrhagia treatment	No	Vuorma, Helsinki Finland, 1996	
Whelan 2003	Breast cancer chemotherapy	Yes	Whelan, Hamilton CA, 1995	included in publication
Whelan 2004	Breast cancer surgery	Yes	Whelan, Hamilton CA, 1997	http://www.fhs.mcmaster.ca/slr/sccru/decisionboard.html

Table 1. Decision aids evaluated in the RCTs (Continued)

Wolf 1996	Prostate specific antigen testing	Yes	Wolf, Charlottesville VA, US, 1996	Script in publication
Wolf 2000	Colon cancer screening	Yes	Wolf, Charlottesville VA, US, 2000	Script in publication
Wong 2006	Pregnancy termination	No	Wong, Nottingham UK, 2002	

a) Prostate specific antigen (PSA) screening

Three of the eight PSA studies compared a decision aid to usual care: Volk 1999 used a 20 minute video plus a brochure on PSA screening; Wolf 1996 used scripted information on PSA screening; and Gattellari 2003 used a 32-page pamphlet.

Gattellari 2005 used the same 32-page pamphlet in a later study, comparing it to both usual care and a group receiving a 20-minute video on testing for prostate cancer. Partin 2004 compared a 23-minute video to both usual care and an information pamphlet. Schapira 2000 compared a detailed decision aid that included quantitative and qualitative information on the risks and benefits of screening with a simple decision aid that had similar content but did not include this information. Frosch 2003 compared a 23-minute video to an internet-based decision aid which mirrored the content of the video. Myers 2005a compared an information booklet and a decision education intervention (that included values clarification, guidance and coaching) to the informational booklet alone.

b) Prenatal screening

Two of three studies compared a detailed to a simple decision aid: Hunter 2005 compared an audio-guided decision aid to individual counselling and group counselling; and Leung 2004 compared an interactive multimedia decision aid to a video and pamphlet. Bekker 2004 compared routine consultation augmented with decision analysis to routine counselling alone.

c) Colon cancer screening

All three studies compared a decision aid to usual care. Pignone 2000 provided the decision aid group with a videocassette, Wolf 2000 used scripted information read to the participants, and Dolan 2002 used an analytic hierarchy process via computer.

d) Genetic testing

Green 2001a compared three groups: decision aid with counselling, counselling alone, and usual care (women on a waiting list served as a control group). In a later study, Green 2004 compared two groups: the decision aid with counselling versus counselling alone. Lerman 1997 compared a decision aid group (discussion and counselling about BRCA1 gene testing) to usual care (women on a waiting list who served as a control group). Schwartz 2001 compared general breast cancer information (usual care) to a booklet decision aid about genetic testing. Miller 2005 compared an enhanced educational intervention to provision of general information about cancer risk (standard care).

e) Hepatitis B vaccination/screening

Clancy 1988 compared a handout and personal decision analysis to usual care.

f) Prostate cancer treatment

Davison 1997 compared a consultation, audiotape, and five handouts about prostate cancer treatment options to usual care recipients who were provided with general information. Auvinen 2004 compared a pamphlet decision aid to standard care by a clinical guideline.

g) Benign prostate disease treatment

Barry 1997 and Murray 2001a compared an interactive videodisc about benign prostate disease treatment with usual care. In Barry 1997 men in the control group were provided with general information, while men in the Murray 2001a trial usual care group did not receive written information.

h) Hormone replacement therapy (HRT)

Two of the nine HRT trials ([McBride 2002](#); [Murray 2001b](#)) compared a decision aid to usual care, with [McBride 2002](#) using a booklet format and [Murray 2001b](#) using an interactive videodisc. Seven HRT trials compared a detailed decision aid that included all of the design elements (options/outcomes, clinical problem, probabilities of outcomes, values clarification, other's opinions, and guidance in decision making and/or communicating) to a simple decision aid that briefly outlined options and outcomes along with some information about the clinical problem. [O'Connor 1998a](#) and [Dodin 2001](#) provided the detailed decision aid group with an audio-guided workbook; [O'Connor 1999a](#) compared an audio-guided decision aid with values clarification and others' opinions to one without values clarification; [Rothert 1997](#) used a combination of a group lecture, handouts and a personal decision exercise; [Rostom 2002](#) compared an audio booklet to a computer version with the same information that also provided feedback to correct misunderstanding of information; [Legare 2003](#) compared an audio-guided decision aid to a general information pamphlet on the benefits and side effects of HRT; and [Deschamps 2004](#) compared an audio-guided decision aid to a 40-minute pharmacist consultation.

i) Ischaemic heart disease

Both studies of ischaemic heart disease compared a decision aid to a usual care. [Morgan 2000](#) used an interactive videodisc with the decision aid group and [Bernstein 1998](#) used a videocassette.

j) Male newborn circumcision

[Herrera 1983](#) compared a pamphlet with a discussion to usual care.

k) Back surgery

[Deyo 2000](#) compared a detailed decision aid (an interactive video plus booklet) to a simple decision aid (booklet alone) for back surgery.

l) Breast cancer surgery

Two studies compared a detailed to a simple decision aid. [Street 1995](#) provided the decision aid group with an interactive multimedia presentation and [Goel 2001](#) used an audio-guided workbook. A third study, [Whelan 2004](#), compared a decision board to usual care.

m) Prophylactic surgery for BRCA1/2 mutation

[vanRoosmalen 2004](#) compared a video and brochure with and without values clarification for women who have tested positive for the BRCA1/2 gene, considering prophylactic surgery.

n) Breast cancer chemotherapy

[Whelan 2003](#) compared a decision board to a general information booklet on adjuvant chemotherapy for women with breast cancer.

o) Atrial fibrillation treatment

Both [Man-Son-Hing 1999](#) and [McAlister 2005](#) compared an audio-guided workbook decision aid to usual care.

p) Dental orthognathic surgery

[Phillips 1995](#) compared a video imaging of facial reconstruction outcomes to usual care.

q) Dental endodontic treatment

[Johnson 2006](#) compared a decision board to usual care.

r) Infant vaccination schedules

[Dunn 1998](#) compared a video plus pamphlet on vaccination schedule choices for infants to usual care recipients who were provided with general information.

s) Treatment for abnormal uterine bleeding

In the context of treatment for abnormal uterine bleeding, [Kennedy 2002](#) compared three interventions: a) video plus booklet and coaching by a nurse; b) video plus booklet alone; and c) usual care. [Vuorma 2003](#) compared a booklet decision aid to usual care.

t) Obstetrical decisions

[Shorten 2005](#) compared a booklet decision aid to usual care for women considering birthing options after a previous cesarean section. [Wong 2006](#) compared a decision aid leaflet to a placebo leaflet for women considering pregnancy termination methods.

u) Cardiovascular risk management

For patients newly diagnosed with hypertension considering drug therapy, [Montgomery 2003](#) compared four groups: decision analysis and informational video and leaflet, decision analysis alone, informational video and leaflet, and usual care. [Lalonde 2006](#) compared a booklet and personal worksheet decision aid to a personal risk profile and informational book in patients diagnosed with hypertension or dyslipidaemia considering drug therapy or lifestyle changes.

v) Osteoporosis treatment

[Oakley 2006](#) compared an audio-guided decision aid to usual care for treatment options to prevent further bone loss.

w) Pre-operative autologous blood donation

For patients undergoing open heart surgery and considering pre-operative autologous blood donation, [Laupacis 2006](#) compared an audio-guided decision aid booklet to usual care.

By definition, all of the patient decision aids included information about the options and outcomes and implicit values clarification. Most patient decision aids included information on the clinical problem (95%) as well as outcome probabilities (85%). Fewer patient decision aids included examples of others' experiences (62%), and less than half included explicit methods to clarify values (49%) or provided extra guidance in the steps of decision making (47%). (see table [Characteristics of included studies](#)).

The comparison interventions ranged from no intervention through to usual care, and general information through to simpler decision aids that varied in their number of elements. However, most simple decision aids provided information about the clinical problem, options, and outcomes. (see table [Characteristics of included studies](#)).

Risk of bias in included studies

We used the Jadad scale ([Jadad 1996](#)) and the criterion of allocation concealment to assess study quality. The Jadad scale allocates two points to randomisation, two points to blinding, and one point to the description of withdrawals. Allocation concealment provides an assessment of how well the allocation schedule was hidden. The break down of the quality scores for each study can be found in the table Characteristics of included studies. All included studies were described as RCTs (mean randomisation score = 1.6 out of 2, SD = 0.6). None of the studies were blinded which would be expected given the nature of the interventions. Documentation of loss to follow up was generally good (mean follow-up score = 0.7 out of 1, SD = 0.5). The overall mean quality score for the 55 included studies was 2.2 out of 5 (SD = 0.9). If blinding were eliminated from the total score, the overall mean quality score would be 2.2 out of 3.

Effects of interventions

At additional [Table 2](#) we provide a summary of the pooled data from the RCTs; see also Additional tables 1 to 6 for outcome data not pooled, and the [Data and analyses](#) section.

Table 2. Summary of pooled outcomes

Outcome	Type of Comparison	Number of Studies	N for Main Intervention	N for Comparison	Effect size (95% CI)	Statistical Significance
Knowledge						
Knowledge (0 to 100 scale) (Analysis 1.1)	DA vs usual care	18	1708	1783	MD 15.18 (11.66 to 18.69)	P < 0.00001*
Knowledge (0 to 100 scale) (Analysis 2.1)	Detailed vs simple DA	9	627	634	MD 4.63 (3.02 to 6.24)	P < 0.00001*
Decisional conflict: DA versus usual care						
Decisional Conflict (0 to 100 scale) - Total (Analysis 1.2.6)	DA vs usual care	10	918	932	MD -6.12 (-8.62 to -3.63)	P < 0.00001*
Decisional Conflict - Uncertainty subscale (Analysis 1.2.1)	DA vs usual care	12	1149	1184	MD -0.94 (-3.29 to 1.40)	P = 0.43

Table 2. Summary of pooled outcomes (Continued)

Decisional Conflict - Uninformed subscale (Analysis 1.2.2)	DA vs usual care	10	906	933	MD -8.31 (-11.85 to -4.78)	P < 0.00001*
Decisional Conflict - Unclear values subscale (Analysis 1.2.3)	DA vs usual care	8	710	723	MD -6.35 (-10.02 to -2.67)	P = 0.0007*
Decisional Conflict - Unsupported subscale (Analysis 1.2.4)	DA vs usual care	8	712	721	MD -5.97 (-10.40 to -1.55)	P = 0.008*
Decisional Conflict - Ineffective choice subscale (Analysis 1.2.5)	DA vs usual care	11	1005	1060	MD -5.69 (-8.93 to -2.46)	P = 0.0006*
Decisional conflict: Detailed vs simple DA						
Decisional Conflict (0 to 100 scale) - Total (Analysis 2.2.6)	Detailed vs simple DA	7	526	497	MD -1.34 (-3.33 to 0.64)	P = 0.19
Decisional Conflict - Uncertainty subscale (Analysis 2.2.1)	Detailed vs simple DA	7	443	422	MD -2.43 (-8.58 to 3.72)	P = 0.44
Decisional Conflict - Uninformed subscale (Analysis 2.2.2)	Detailed vs simple DA	5	322	290	MD -1.32 (-5.27 to 2.62)	P = 0.51
Decisional Conflict - Unclear values subscale (Analysis 2.2.3)	Detailed vs simple DA	5	319	290	MD -1.05 (-4.81 to 2.70)	P = 0.58
Decisional Conflict - Unsupported subscale (Analysis 2.2.4)	Detailed vs simple DA	5	324	290	MD -0.80 (-3.77 to 2.17)	P = 0.6

Table 2. Summary of pooled outcomes (Continued)

Decisional Conflict - Ineffective choice subscale (Analysis 2.2.5)	Detailed vs simple DA	5	324	289	MD -0.04 (-3.93 to 3.86)	P = 0.99
Participation in decision making						
Participation in decision making (DM) - Patient controlled (Analysis 1.3.1)	DA vs usual care	7	550	556	RR 1.65 (1.02 to 2.65)	P = 0.04*
Participation in DM - Shared (Analysis 1.3.2)	DA vs usual care	7	550	565	RR 0.99 (0.78 to 1.25)	P = 0.93
Participation in DM - Practitioner controlled (Analysis 1.3.3)	DA vs usual care	8	630	647	RR 0.61 (0.45 to 0.82)	P = 0.0009*
Behaviour: Remaining undecided						
Remaining undecided (Analysis 1.6)	DA vs usual care	4	516	516	RR 0.51 (0.34 to 0.75)	P = 0.0006*
Remaining undecided (Analysis 2.5)	Detailed vs simple	2	148	144	RR 1.04 (0.66 to 1.62)	P = 0.87
Preference or uptake of option: DA versus usual care						
Preference or uptake of option - Surgery (ITT analysis, Analysis 1.7.2)	DA vs usual care	8	1028	1041	RR 0.75 (0.60 to 0.94)	P = 0.01*
Preference or uptake of option - Prostate Specific Antigen testing (Analysis 1.8)	DA vs usual care	5	726	716	RR 0.80 (0.66 to 0.98)	P = 0.03*

Table 2. Summary of pooled outcomes (Continued)

Preference or uptake of option - Colon cancer screening (Analysis 1.9)	DA vs usual care	3	435	300	RR 1.14 (0.70 to 1.85)	P = 0.59
Preference or uptake of option - Breast cancer genetic testing (Analysis 1.10)	DA vs usual care	4	448	501	RR 1.01 (0.83 to 1.22)	P = 0.94
<i>Preference or uptake of option: Detailed versus simple DA</i>						
Preference or uptake of option - Surgery (ITT analysis, Analysis 2.5.2)	Detailed vs simple DA	2	220	233	RR 0.78 (0.57 to 1.07)	P = 0.12
Preference or uptake of option - Prostate Specific Antigen testing (Analysis 2.6)	Detailed vs simple DA	3	336	341	RR 0.97 (0.81 to 1.17)	P = 0.78
Preference or uptake of option - Hormone replacement therapy (Analysis 2.7)	Detailed vs simple DA	3	181	176	RR 0.73 (0.55 to 0.98)	P = 0.04*
Preference or uptake of option - Prenatal diagnostic testing (Analysis 2.8)	Detailed vs simple DA	2	216	227	RR 0.94 (0.85 to 1.04)	P = 0.22
<i>Accurate risk perceptions</i>						
Accurate risk perceptions (Analysis 3.1)	DA with outcomes and probabilities vs no outcome probabilities	11	1504	1449	RR 1.61 (1.35 to 1.92)	P < 0.00001*

Table 2. Summary of pooled outcomes (Continued)

Accurate risk perceptions (Analysis 3.2)	- Numbers	8	994	1017	RR 1.81 (1.43 to 2.29)	P < 0.00001*
Accurate risk perceptions (Analysis 3.3)	- Words	3	510	432	RR 1.27 (1.09 to 1.48)	P = 0.002*

MD: mean difference.
RR: relative risk.
CI: confidence interval.

IPDAS attributes of the decision: whether the patient decision aid improves the match between the chosen option and the features that matter most to the informed patient.

The RCTs used three measures which correspond to this definition: knowledge test results, accuracy of risk perceptions, and value congruence with the chosen option.

Knowledge

Twenty-seven of the 55 studies examined the effects of decision aids on knowledge; 18 of these compared decision aids to usual care and 9 compared detailed decision aids to simple decision aids. The studies' knowledge tests were based on information contained in the decision aid, thereby establishing content validity. The proportion of accurate responses was transformed to a percentage scale ranging from 0% (no correct responses) to 100% (perfectly accurate responses). The results are reported separately for the comparison of decision aids to usual care and the comparison of decision aids with detailed information to simpler decision aids. One additional study, [Partin 2004](#), used a previously validated 10-item prostate cancer knowledge index to assess patient's prostate cancer screening knowledge. Patients in the decision aid group scored moderately higher on the index than control group patients (see [Table 3](#)).

Table 3. Other outcome measures

Study	Scale Used	Timing	N Decision Aid	DA - mean	N Comparison	Comparison - mean	Notes
<i>Knowledge</i>							
Partin 2004	10-item knowledge in-	2 weeks	308	7.44	290	6.9	P = 0.001

Table 3. Other outcome measures (Continued)

	dex score						
<i>Expectations</i>							
Phillips 1995	Ex- pectations 18- item scale with response range -3 to +3	2 weeks	37	78%	37	62%	DA sig (P = 0.045) higher self-image ex- pectation. No difference (P > 0.13) for oral function, gen- eral well- being, general health. Hav- ing a higher expectation was not neces- sarily correct.
Laupacis 2006	Re- alistic expecta- tion of out- comes 8-item questionnaire (0 to 100)	average 10 days	47	21.5 (18.1 SD)	50	7.0 (7.6 SD)	P = 0.001
Street 1995	Optimism 8-item instru- ment (range 8 to 40)	post- intervention	30	34.1 (change from baseline +0.3)	30	33.8 (change from baseline +0.8)	No difference. The more women know about their treat- ment options, the more posi- tive they were.
<i>Value congruence with chosen option</i>							
Rothert 1997	Correlation between ex- pected utilities and their like- lihood of tak- ing hormones	-----	-----	-----	-----	-----	Simple DA showed lower correla- tions between expected value of hormones and likelihood of taking hor- mones than did more detailed DA

Table 3. Other outcome measures (Continued)

O'Connor 1999a	De- gree to which personal val- ues discrimi- nated between the choices women made	immediately after	101	65% (48.7%SD)	100	67% (48.5% SD)	No difference between groups in dis- crimination of personal val- ues amongst choices; in small group accepting HRT, there was a non-sig- nificant trend toward bet- ter discrimina- tion (P = 0.06) in the values clarification group (40%) than the con- trol (0%)
Dodin 2001	Congru- ence between personal val- ues and de- cision 4-items using a 0 to 10 scale	post DA	52	23%	49	14%	P = 0.003
Lerman 1997	Association between val- ues and choice						No difference; between group differ- ences were not reported
Decisional Conflict Score - Patient/Physician Agreement							
Legare 2003	DCS / Dolan's Provider De- cision Process Assessment Instrument	immediately post	97	ICC 0.44 (0.9 SD)	87	ICC 0.28 (1.0 SD)	
Decision Making Preference							
Barry 1997	15-item sub- scale of Au- tonomy Pref- erence Index	6, 12 months	104	40.4 (6 months), 39.0 (12 months)	123	40.4 (6 months), 39.3 (12 months)	No difference (P = 0.69)

Table 3. Other outcome measures (Continued)

	to measure interest in participating							
Satisfaction								
Miller 2005	Satisfaction with Cancer Information Service 1-item (1 to 5; low to high)	2 weeks		4.37 (0.84 SD)		4.38 (0.86 SD)		no difference
		6 months		4.51 (0.75 SD)		4.51 (0.64 SD)		no difference
Deschamps 2004	Satisfaction with Preparation for Decision Making (10-item)	Post-physician consult	48	28 (6.1 SD)	42	27(5.5 SD)		ns
Oakley 2006	Satisfaction with Information about Medicines (0-17; low-high)	4 months post	16	10.4 (2.9 SD)	17	10.1 (2.2 SD)		ns
Hunter 2005	Satisfaction with genetic counselling 11-item short form (range 4 to 44; low to high)	immediately post	116	37.27 (5.74 SD)	126	40.48 (4.26 SD)		P < 0.001
Satisfaction - Decision Making Process								
Deyo 2000	7-item scale (5 point response)	3 months	171	separate responses provided with no total	172	separate responses provided with no total		No difference except DA more likely to report they had as much information as they wanted and less likely to report having relied too much

Table 3. Other outcome measures (Continued)

							on physician's opinion
Man-Son-Hing 1999	6-item survey using a 5-point Likert scale	1 to 4 days	146	83.75% (14.79)	138	84.75% (13.04)	No difference
Laupacis 2006	information subscale 4-item (0 to 100; low to high)	average days	10 54	76 (15.5 SD)	56	59 (23.3 SD)	P = 0.001
Laupacis 2006	practitioner treatment subscale 4-item (0 to 100; low to high)	average days	10 54	69 (25.3 SD)	56	54 (26.7 SD)	P = 0.004
Green 2004	Effectiveness of consultation - patient assessment. Single item 1 (not at all effective) to 7 (extremely effective)		106	6.6	105	6.6	No difference
Green 2004	Effectiveness of consultation - counsellor assessment. Single item 1 to 7			5.9		5.8	No difference
Satisfaction - Decision							
Deschamps 2004	6-item	3 months	46	85.0 (12.5)	41	82.5 (15.0)	ns
Rothert 1997	6-item scale (measured on 1 to 5)	1 day	83	4.0 (0.56)	89	3.8 (0.66)	No difference
		6 months	63	3.8 (0.63)	75	3.8 (0.67)	No difference
		12 months	62	3.9 (0.62)	74	3.9 (0.67)	No difference

Table 3. Other outcome measures (Continued)

Laupacis 2006	1-item (0 to 100; low to high)	average 10 days	54	73 (21.7)	56	61 (25.4)	P = 0.015
Deschamps 2004	6-item	3 months	46	85.0 (12.5)	41	82.5 (15.0)	ns
Volk 1999	6-item	1 year	70	24.3 (2.8)	67	23.8 (3.8)	ns
Confidence							
McBride 2002	Confidence with ability to understand outcomes of HRT, make a decision, engage in discussion with practitioner 3-items (0 to 10; low to high confidence)	1 month post	273	78% (18% SD)	284	70% (19% SD)	P < 0.0001
		9 months post	261	80% (17%SD)	278	75% (20% SD)	P = 0.0004
Rothert 1997	8-items (1 to 10; low to high confidence)	post DA	83	78% (16% SD)	89	80% (19% SD)	No difference
		12 months post	63	78% (15% SD)	74	80% (19% SD)	No difference
Gattellari 2003	Perceived ability to make an informed choice 1-item; 5-point Likert scale	3 days post	106		108		P = 0.008; DA group more likely to agree that they could make an informed choice about PSA screening
Gattellari 2005	Perceived ability to make an informed choice 1-item; 5-point Likert scale	Immediately post	131		136		No difference
Healthcare system effects							

Table 3. Other outcome measures (Continued)

Deyo 2000	Healthcare use	1 year	171	-----	172	-----	No difference in most services; DA less surgery for herniated disk
Bekker 2004	Consultation length (minutes)		50	32.2 (13.0 SD)	56	26.3 (11.5 SD)	P = 0.01
Green 2004	Consultation length (minutes)		106	82	105	90	P = 0.03
Whelan 2003	Consultation length (minutes)		50	68.3	50	65.7	P = 0.53

In the comparison of patient decision aids to usual care (Barry 1997; Bekker 2004; Bernstein 1998; Dunn 1998; Gattellari 2003; Gattellari 2005; Green 2001a; Johnson 2006; Laupacis 2006; Lerman 1997; Man-Son-Hing 1999; Montgomery 2003; Morgan 2000; Schwartz 2001; Shorten 2005; Volk 1999; Whelan 2003; Wong 2006), people exposed to decision aids had higher average knowledge scores (MD 15.2%; 95% CI 11.7 to 18.7; Analysis 1.1). The nine studies comparing detailed to simpler patient decision aids (Dodin 2001; Goel 2001; Hunter 2005; O'Connor 1998a; Rostom 2002; Deyo 2000; Rothert 1997; Street 1995; Schapira 2000) showed a smaller statistically significant beneficial effect (MD 4.6%; 95% CI 3.0 to 6.2; Analysis 2.1).

Accurate risk perceptions (i.e. perceived probabilities of outcomes)

Eleven of 55 studies examined the effects of including probabilities in decision aids on the accuracy of patients' perceived probabilities of outcomes. Eight studies measured perceived probabilities as percentages (Dodin 2001; Gattellari 2003; Man-Son-Hing 1999; McAlister 2005; McBride 2002; O'Connor 1998a; Whelan 2003; Whelan 2004) and three gauged probabilities in words (Lerman 1997; Schapira 2000; Wolf 2000).

Perceived outcome probabilities were classified according to the percentage of individuals whose judgments corresponded to the scientific evidence about the chances of an outcome for similar people. In three out of four studies that elicited expectations for multiple outcomes (Dodin 2001; McAlister 2005; O'Connor 1998a), the proportion of realistic expectations was averaged; in

the remaining study (Man-Son-Hing 1999), the most conservative result was chosen for meta-analysis.

People who received a detailed patient decision aid with descriptions of outcomes and probabilities were more likely to have accurate risk perceptions than those who did not receive this information; the pooled relative risk (RR) of having accurate risk perceptions was 1.6 (95% CI 1.4 to 1.9; Analysis 3.1). There was a trend towards a stronger effect when probabilities were measured quantitatively versus qualitatively. The pooled RR for probabilities described as numbers was 1.8 (95% CI 1.4 to 2.3; Analysis 3.2). The pooled RR for probabilities described in words was 1.3 (95% CI 1.1 to 1.5; Analysis 3.3).

Value congruence with chosen option

Four of 55 studies measured value congruence with chosen option; however, Lerman (Lerman 1997) did not calculate differences between interventions. The three trials comparing interventions were similar in that they: a) focused on the decision to take menopausal hormone replacement therapy (HRT); and b) compared two active interventions. However, these trials used different measures of value congruence. Holmes-Rovner (Rothert 1997) measured the correlation between the subjective expected value of hormones and women's likelihood of taking HRT, converted here to percent of variance in likelihood explained by values. Dodin 2001 measured the percentage of variance in decisions explained

by values. O'Connor 1999a used logistic regression to estimate the percentage agreement between values and choice. Patient decision aids improved value congruence with chosen option in two of three studies. In Dodin 2001, 24% of the variance in HRT decisions was explained by personal values when a detailed decision aid with explicit values clarification was used; in contrast 14% of the variance in decisions was explained when a simpler decision aid was used ($P = 0.003$). In the study by Holmes-Rovner (Rothert 1997), the percentage of variance in likelihood of choosing HRT that was explained by women's expected values was greater when a more detailed decision aid was used (13 to 14%) than when a simpler decision aid was used (0.1 to 2%). O'Connor (O'Connor 1999a) found that the addition of an explicit values clarification exercise in a decision aid did not improve agreement between values and chosen option. However, in the subgroup of women who chose HRT, women who used the decision aid with explicit values clarification had a trend toward better agreement (40%) than those who used an identical decision aid without explicit values clarification (0%), $P = 0.06$.

IPDAS attributes of the decision process: whether the patient decision aid helps patients to: recognize that a decision needs to be made; know the options and their features; understand that values affect the decision; be clear about the option features that matter most; discuss values with their practitioner; and become involved in preferred ways.

In relation to the IPDAS decision process criteria, no trials evaluated the extent to which patient decision aids helped patients to: recognize that a decision needs to be made, understand that values affect the decision, or discuss values with their practitioner. Although eight trials evaluated the effects on patient participation, none focused on helping patients become involved in preferred ways.

Some studies measured patients' self-reports about feeling informed and clear about personal values. The measures used to evaluate these two criteria were two subscales of the previously validated Decisional Conflict Scale (DCS) (O'Connor 1995).

Decisional conflict

Seventeen studies evaluated decisional conflict using the DCS (O'Connor 1995). The DCS is reliable, discriminates between those who make or delay decisions, is sensitive to change, and discriminates between different decision support interventions (Morgan 2000; O'Connor 1995; O'Connor 1998a). The scale measures the constructs of uncertainty and factors contributing to uncertainty (such as feeling uninformed, unclear about values, and unsupported in decision making). A final subscale measures perceived effective decision making. The scores were standardized to range from zero (no decisional conflict) to 100 points (extreme

decisional conflict). Scores of 25 or lower are associated with follow-through with decisions, whereas scores that exceed 38 are associated with delay in decision making (O'Connor 1998a). When decision aids are compared to usual care, a negative score indicates a reduction in decisional conflict, which is in favour of the decision aid.

Analysis 1.2.6 summarizes the decisional conflict results for the 10 studies that compared decision aids to usual care (Dolan 2002; Laupacis 2006; Man-Son-Hing 1999; McAlister 2005; Montgomery 2003; Morgan 2000; Murray 2001a; Murray 2001b; Shorten 2005; Whelan 2004) and Analysis 2.2.6 summarises the results for the 7 studies that compared detailed to simple decision aids (Dodin 2001; Goel 2001; Hunter 2005; Lalonde 2006; Legare 2003; O'Connor 1998a; O'Connor 1999a).

Among the 17 studies, the decision aids were significantly better at reducing total decisional conflict in 8 studies: 7 comparing decision aids to usual care (Laupacis 2006; McAlister 2005; Montgomery 2003; Murray 2001a; Murray 2001b; Shorten 2005; Whelan 2004) and 1 comparing detailed to simple decision aids (O'Connor 1998a). Reductions ranged from -2.5 to -17.1 out of 100. Smaller reductions ranging from -1.5 to -5.0 out of 100 were noted in 5 trials but were not statistically significant: 2 comparing decision aids to usual care (Dolan 2002; Man-Son-Hing 1999) and 3 comparing detailed versus simple decision aids (Goel 2001; Hunter 2005; Legare 2003). Morgan 2000 showed no difference between decision aids and usual care and Dodin 2001 and Lalonde 2006 showed no difference between detailed and simple decision aids. When a decision aid with values clarification was compared to the same decision aid without values clarification (O'Connor 1999a), there was a small increase of 2.5 in total decisional conflict but it was not statistically significant. The overall MD was -6.1 out of 100 points for decision aid/usual care comparisons (95% CI -8.6 to -3.6; Analysis 1.2.6) and -1.3 for detailed/simple decision aid comparisons (95% CI -3.3 to 0.6; Analysis 2.2.6).

Fifteen trials used the DCS subscale for feeling informed and 13 trials used the DCS subscale for feeling clear about values. Because this DCS subscale measures self-reported comfort with knowledge and not actual knowledge, we elected to consider it a process measure and to reserve the gold standard of objective knowledge tests in assessing decision quality.

The MD in feeling uninformed about options, benefits, and harms was -8.3 (95% CI -11.9 to -4.8; Analysis 1.2.2) in the ten trials that compared patient decision aids to usual care (Bekker 2004; Dolan 2002; Laupacis 2006; Man-Son-Hing 1999; McAlister 2005; Montgomery 2003; Morgan 2000; Murray 2001a; Murray 2001b; Wong 2006). The five trials that compared detailed with simpler patient decision aids (Dodin 2001; Goel 2001; Lalonde 2006; O'Connor 1998a; O'Connor 1998a) had a MD in feeling uninformed of -1.3 (95% CI -5.3 to 2.6; Analysis 2.2.2).

Eight trials comparing patient decision aids to usual care (Dolan 2002; Laupacis 2006; Man-Son-Hing 1999; McAlister 2005; Montgomery 2003; Morgan 2000; Murray 2001a; Murray 2001b)

had a MD of -6.4 (95% CI -10.0 to -2.7) for feeling clear about values (Analysis 1.2.3). Five trials compared detailed to simpler decision aids (Dodin 2001; Goel 2001; Lalonde 2006; O'Connor 1998a; O'Connor 1999a). For these trials, the MD in feeling clear about values was -1.1 (95% CI -4.8 to 2.7; Analysis 2.2.3).

Two trials measured the longer term effect of decision aids (compared to usual care) on total decisional conflict, overall uncertainty, factors contributing to uncertainty, and perceived effective decision making. In both trials, the statistically significant differences observed at three months post intervention were maintained at nine months (Murray 2001a; Murray 2001b).

Patient-practitioner communication

Legare 2003 measured agreement between physicians and women on decisional conflict scores and found that the agreement measure was higher for the decision aid group than for the controls.

Participation in decision making

Eight studies (Auvinen 2004; Davison 1997; Dolan 2002; Man-Son-Hing 1999; Morgan 2000; Murray 2001a; Murray 2001b; Whelan 2003) compared the effects of decision aids to usual care in terms of participation in decision making (Analysis 1.3) and one study (Deschamps 2004) compared a detailed decision aid to a simpler one (Analysis 2.3). The Davison paper used the Control Preferences Scale (Degner 1992). The scale measures the preferred or actual role in decision making using five response statements: two represent an active or patient controlled role, one a shared or collaborative role, and two response statements represent a passive or practitioner controlled role. The eight other studies used comparable response statements that could be classified within each of the three groupings of the Control Preferences Scale. We present data on actual role in decision making in this review.

Seven of these 9 studies showed a 16 to 70% reduction in the proportion of people who assumed a passive (practitioner-controlled) role in decision making; in two trials this reduction was statistically significant (Auvinen 2004; Davison 1997) and in five it was not (Deschamps 2004; Man-Son-Hing 1999; Morgan 2000; Murray 2001b; Whelan 2003). The other two studies showed a non-significant increase (Dolan 2002; Murray 2001a). The pooled RR comparing decision aids to usual care was 0.6 (95% CI 0.5 to 0.8; Analysis 1.3.3). A mirrored pattern emerged for individuals assuming an active (patient-controlled) role in decision making. Three of the nine studies (Auvinen 2004; Davison 1997; Murray 2001a) reported RRs ranging from 3.4 to 7.6, indicating a significant impact on the assumption of the patient-controlled role, three indicated an increase that was not statistically significant, and there was a non-significant decrease for the other two studies. The pooled RR for decision aid versus usual care was 1.7 (95% CI 1.0 to 2.7; Analysis 1.3.1). The proportion adopting a shared decision making role was more variable (decision aid versus usual care pooled RR 1.0; 95% CI 0.8 to 1.3; Analysis 1.3.2).

One study (Barry 1997) found no significant difference between the decision aid and usual care, using a 15-item decision-making preference subscale of the previously validated Autonomy Preference Index (Ende 1989) (see Table 3).

Satisfaction

Six out of 11 studies found improvements in satisfaction with: the decision; process of decision making; opportunities to participate in decision making; and/or outcomes.

Satisfaction with the decision making process was measured in 6 trials. Three trials comparing the decision aid to usual care (Barry 1997; Bernstein 1998; Morgan 2000) used the 12-item validated questionnaire (Barry 1997) (Analysis 1.4). The scores were standardized to a 0 to 100 point scale, with higher scores reflecting greater satisfaction. One of these three studies (Barry 1997) demonstrated that decision aids significantly improved satisfaction with the decision making process by 5 points out of 100. Morgan 2000 showed an improvement of 2 points out of 100 and Bernstein 1998 showed a worsening of satisfaction by 3 points of 100 but neither of these results were statistically significant.

Three other studies (Deyo 2000; Laupacis 2006; Man-Son-Hing 1999) evaluated satisfaction with the process of decision making, using different measures (see Table 3). Deyo 2000 found mixed results, with separate items measuring satisfaction; results for two out of the nine items were statistically significantly different, with the decision aid group reporting higher levels of satisfaction. Laupacis 2006 found statistically significant greater satisfaction with decision aids over usual care, on two scales measuring satisfaction with information and satisfaction with practitioner treatment. Man-Son-Hing 1999 found no statistically significant difference between groups (MD 1%).

Nine trials measured satisfaction with the decision. Three trials (Barry 1997; Bernstein 1998; Morgan 2000) used the three-item validated Satisfaction with Decision Made questionnaire (Barry 1997) (Analysis 1.5). The scores were standardized to a 0 to 100 point scale, with higher scores reflecting greater satisfaction. The differences between decision aids and usual care for individual's satisfaction with the decision ranged from 2.5 to -5.0 out of 100 and were not statistically significantly different. In 4 of 6 other trials using different measures to evaluate satisfaction with the decision (see Table 3), there were no statistically significant differences between decision aids and comparison interventions (Deschamps 2004; Deyo 2000; Rothert 1997; Volk 1999). McBride 2002 and Laupacis 2006 found that the decision aid group was statistically significantly more satisfied (5% and 12% MD respectively).

Kennedy 2002 measured satisfaction with opportunities to participate in decision making and with overall results of treatment, using two single item questions. Compared to usual care, women who received the decision aid followed by nurse coaching were statistically significantly more satisfied with the opportunities to participate in decision making (OR 1.5; 95% CI 1.1 to 2.0) and

more satisfied with their results of treatment (OR 1.4; 95% CI 1.0 to 2.0). [Deschamps 2004](#) evaluated satisfaction with preparation for decision making using a 10-item scale. There was no statistically significant difference between the decision aid group or the control group participants who received a 40-minute pharmacist consultation. [Oakley 2006](#) and [Miller 2005](#) used specific measures of satisfaction with information and found no difference between groups. Lastly, [Hunter 2005](#), found a small but statistically significant higher satisfaction with genetic counselling score for those who received individual counselling versus a decision aid. (See [Table 3](#)).

Behaviour

Proportion undecided

Four studies comparing decision aids to usual care reported on the proportion of people who remained undecided post intervention. Three of these studies ([Man-Son-Hing 1999](#); [Murray 2001b](#); [Vuorma 2003](#)) showed statistically significantly lower proportion in the decision aid group ([Analysis 1.6](#)). For individuals considering warfarin post atrial fibrillation, 1% of those in the decision aid group remained undecided, compared to 6% of those who received usual care ([Man-Son-Hing 1999](#)). For women considering HRT, 14% in the decision aid group, versus 26% in the usual care group, remained undecided three months after using the decision aid. A similar pattern was observed at the nine month follow-up, with 6% versus 14% remaining undecided ([Murray 2001b](#)). In [Vuorma 2003](#) evaluating the menorrhagia decision aid, 4% of parents in the decision aid group were undecided, versus 11% in the usual care group. In [Shorten 2005](#) for women considering vaginal birth after previous cesarean section, 14% of women in the decision aids group remained undecided versus 22% in the usual care group. The pooled RR was 0.5 (95% CI 0.3 to 0.8). The trials ([Leung 2004](#); [Deschamps 2004](#)) comparing detailed decision aids to simpler ones found no statistically significant differences (pooled RR 1.0; 95% CI 0.7 to 1.6; [Analysis 2.4](#)).

Decisions: preferences and uptake of options

Forty-two trials assessed the effects of decision aids on the participants' preferred options ($n = 19$) or their uptake of options ($n = 23$). Preferences or uptake of options were reported as the percentage of individuals stating a preference for, or actually implementing, the most intensive or most invasive option. Ten trials focused on choices regarding major elective surgery. Eight ([Auvinen 2004](#); [Barry 1997](#); [Bernstein 1998](#); [Kennedy 2002](#); [Morgan 2000](#); [Murray 2001a](#); [Vuorma 2003](#); [Whelan 2004](#)) compared decision aids to usual care ([Analysis 1.7](#)) and two ([Deyo 2000](#); [Street 1995](#)) compared detailed to simple decision aids ([Analysis 2.5](#)). Using intention-to-treat analysis, three trials

showed a statistically significant reductions in surgery rates: 29% for cardiac revascularization ([Morgan 2000](#)); 74% for mastectomy ([Whelan 2004](#)); and 33% for prostatectomy ([Auvinen 2004](#)). Four out of ten trials ([Barry 1997](#); [Bernstein 1998](#); [Deyo 2000](#); [Kennedy 2002](#)) showed reductions in uptake of the more intensive surgical treatment by 18% to 42%, but the results were not statistically significant. One study ([Vuorma 2003](#)) showed non-significant higher rates of hysterectomy in the decision aid group (53%) compared to usual care (49%) at 1 year post-intervention. Another study ([Murray 2001a](#)), having less than 1% weight in the pooled results, reported a non-significant 5-fold increase in uptake of prostatectomy. There was no difference in the uptake rate of mastectomy in [Street 1995](#). There was a statistically significant reduction in major elective surgery for decision aid compared to usual care (RR 0.8; 95% CI 0.6 to 0.9; [Analysis 1.7.2](#)) but the reduction for detailed compared to simple decision aids was not statistically significant (RR 0.8; 95% CI 0.6 to 1.1; [Analysis 2.5.2](#)). Using as-treated analysis, the reduction in surgical rates were similar for decision aid compared to usual care (RR 0.8; 95% CI 0.6 to 0.9; [Analysis 1.7.1](#)) and for detailed compared to simple decision aids (RR 0.8; 95% CI 0.6 to 1.0; [Analysis 2.5.1](#)).

Three trials evaluated the effect of decision aids versus usual care on minor elective surgical decisions. Decision aids did not significantly influence circumcision rates ([Herrera 1983](#)), surgical abortion rates ([Wong 2006](#)), or preferences for dental orthognathic surgery ([Phillips 1995](#)).

The effects of eight decision aids on Prostate Specific Antigen (PSA) screening decisions were variable. In two out of five studies comparing decision aids with usual care, there were significant reductions in preference for screening by 23% and 42% ([Volk 1999](#); [Wolf 1996](#)) ([Analysis 1.8](#)). Two studies ([Gattellari 2005](#); [Partin 2004](#)) showed reductions of 9% and 10% respectively, and one study ([Gattellari 2003](#)) showed an increase of 10%; however, these results were not statistically significant. The pooled RR was 0.8 (95% CI 0.7 to 1.0). Of the three studies that compared a detailed and simpler decision aid ([Analysis 2.6](#)), there was a statistically significant reduction of PSA screening by 11% in one study ([Frosch 2003](#)); a non-significant reduction of 2% in a second study ([Schapira 2000](#)); and a non-significant increase of 89% in the third study ([Myers 2005a](#)). The pooled RR was 1.0 (95% CI 0.8 to 1.2).

In one of three studies of colon cancer screening, the decision aid significantly increased uptake of screening by 64% ([Pignone 2000](#)) compared to usual care. However, there was no significant impact on preferences in another study ([Wolf 2000](#)), in which the relative increment was 9%. In the third study, [Dolan 2002](#), there was a decrease in screening by 73% that was not statistically significant. The pooled RR was not statistically significant (RR 1.1; 95% CI 0.7 to 1.9) ([Analysis 1.9](#)).

Preferences for breast cancer gene screening were not statistically significantly affected when a decision aid was compared to usual care. One study reported an increased uptake of screening by 14%

(Lerman 1997), a second study reported an increase of 18% (Green 2001a), a third study reported a decrease in uptake by 29% (Schwartz 2001), the last study reported no difference (Green 2004). The pooled RR was 1.0 (95% CI 0.8 to 1.2; Analysis 1.10). The uptake of prenatal testing was not affected by a decision aid compared to usual care (Bekker 2004, RR 1.1, 95% CI 0.9 to 1.2) nor by a more complex decision aid compared to a simple decision aid (Hunter 2005; Leung 2004; pooled RR 0.9, 95% CI 0.9 to 1.0; Analysis 2.8).

Preferences regarding hormone replacement therapy were affected when a detailed decision aid was compared to a simple decision aid, with a statistically significant decrease of 36% (Dodin 2001), a decrease of 25% (Deschamps 2004) and an increase of 12% that were not statistically significant (O'Connor 1998a). There was a statistically significant reduction of 27% in uptake of hormone replacement therapy of when these studies were pooled (RR 0.7; 95% CI 0.6 to 1.0; Analysis 2.7). In a single trial comparing a decision aid to usual care (Murray 2001b), there was a decrease of 8% which was not statistically significant.

Two trials evaluated the effect of a decision aid on use of anti-thrombotic therapy for atrial fibrillation versus usual care. One trial demonstrated a non-significant reduction of uptake of warfarin of 25% (Man-Son-Hing 1999). The second trial evaluated the proportion of patients choosing the option that was appropriate relative to their level of risk, and found no significant difference between the groups (McAlister 2005).

Montgomery 2003 found no significant effect of decision aids over usual care on the uptake of medication for hypertension, and Whelan 2003 also found no significant effect on preference for adjuvant chemotherapy for breast cancer.

In three other studies comparing decision aids to usual care, there was a statistically significant increase in uptake of Hepatitis B vaccination by 76% (Clancy 1988), but no effect on preferences for vaginal birth following previous cesarean section (Shorten 2005) or on the uptake of pre-operative autologous blood donation (Laupacis 2006).

Continuance (adherence) with chosen option

Five studies measured continuance with the chosen option or adherence. Three of these studies compared decision aids to usual care (Man-Son-Hing 1999; Oakley 2006; Montgomery 2003) and two compared detailed to simpler decision aids (Deschamps 2004; Rothert 1997). Man-Son-Hing 1999, comparing an audiotape booklet decision aid to usual care, measured continuance with the chosen option (warfarin versus aspirin) at six months and found no significant difference between the groups. Oakley 2006 compared an audiotape booklet decision aid to usual care; there was no difference between the groups in adherence to oral bisphosphonate medication at 4 months. Montgomery 2003 compared four groups: decision analysis plus informational video and leaflet; decision analysis; informational video; and usual care. There was no difference for any of the interventions in adherence to blood pressure medication at three years. The two studies which compared a detailed to a simpler decision aid measured adherence to hormone replacement therapy at 12 months: Rothert 1997 compared an informational lecture and personal decision exercise to a pamphlet and Deschamps 2004 compared an audiotape booklet decision aid to a pharmacist consultation. Neither study found a difference between the decision aid and comparison group (Table 4).

Table 4. Continuance (adherence) with chosen option

Reference	Timing	N Decision Aid	Mean (SD) Decision Aid	N Comparison	Mean (SD) Comparison	Notes
<i>DA versus usual care</i>						
Oakley 2006	4 months	16	10.4% (32) [improvement from baseline]	17	2% (26) [improvement from baseline]	Not significant
Man-Son-Hing 1999	6 months	129	95.35%	134	93.28%	P = 0.44
Montgomery 2003	~ 3 years					No difference
<i>Detailed versus simpler DA</i>						

Table 4. Continuance (adherence) with chosen option (*Continued*)

Rothert 1997	12 months	62	~89%	74	~89%	No difference
Deschamps 2004	12 months	16	~72%	20	~72%	No difference

Health outcomes

General health outcomes

Seven studies compared a decision aid to usual care in terms of general health outcomes. Six of these ([Barry 1997](#); [Bernstein 1998](#); [Kennedy 2002](#); [Morgan 2000](#); [Murray 2001a](#); [Murray 2001b](#)) used the previously validated Medical Outcomes Study 36-item Short-Form Health Survey (SF-36) or the 12-item Short-form Health Survey (SF-12) ([Stewart 1992](#)); and, one study ([Vuorma 2003](#)) used the RAND-36 ([Hays 1993](#)). As shown in [Table 5](#), there were no significant differences for mental health function or social function in all seven studies. In one study ([Barry 1997](#)), general health and physical function outcome scores were significantly better in the decision aid group compared to usual care for men considering treatments for benign prostatic disease. Of the two studies evaluating the effect of a decision aid for women considering treatment for abnormal uterine bleeding, [Kennedy 2002](#) found a statistically significant improvement in role physical function and [Vuorma 2003](#) found a statistically significant improvement in emotional role functioning for women.

Table 5. General health outcomes

Reference	Timing	N Decision Aid	Mean (SD)	DA Change from Base-line	N Comparison	Mean Comparison (SD)	Change from Base-line	Notes
<i>General health</i>								
Barry 1997 (SF-36)	Baseline	104	67.2 (19.0)		123	71.1 (17.6)		P = 0.02
	3 months			-0.96 (1.41)			-3.59 (1.57)	
	6 months			-1.46 (1.41)			-4.93 (1.45)	
	12 months			0.61 (1.58)			-4.99 (1.44)	
Morgan 2000 (SF-36)	6 months post	72	62 (23)	+4.0	88	65 (20)	+7.0	No difference

Table 5. General health outcomes (Continued)

Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		2.2	159		2.8	No difference
Physical function								
Barry 1997 (SF-36)	Baseline	104	81.9 (20.0)		123	83.0 (18.9)		P = 0.02
	3 months			-0.34 (1.61)			-1.81 (1.07)	
	6 months			0.10 (1.28)			-3.26 (1.37)	
	12 months			0.15 (1.40)			-3.74 (1.18)	
Bernstein 1998 (SF-12)	3 months post	61	38 (12.1)	+0.6	48	37.6 (10.6)	+3.8	No difference
Morgan 2000 (SF-36)	6 months post	72	67 (29)	+7.0	88	71 (24)	+10.0	No difference
Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		2.4	159		2.2	No difference
Social function								
Barry 1997 (SF-36)	Baseline	104	90.6 (15.5)		123	91.7 (15.7)		P = 0.17
	3 months			0.34 (1.58)			-2.26 (1.36)	
	6 months			-0.05 (1.92)			-2.46 (1.45)	
	12 months			-1.46 (1.85)			-3.52 (1.71)	
Kennedy 2002 (SF-36)	2 years	176			157			No difference

Table 5. General health outcomes (Continued)

Vuorma 2003 (RAND-36)	1 year	156		5.2	159		7.1	No difference
Mental function								
Bernstein 1998 (SF- 12)	3 months post	61	49.1 (11.4)	0.0	48	48.9 (10.8)	+0.9	No difference
Kennedy 2002 (SF- 36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		4.7	159		5.3	No difference
Role function								
Morgan 2000 (SF- 36)	6 months post	72	62 (44)	+20.0	88	58 (43)	+15.0	No difference
Kennedy 2002 (SF- 36)	2 years	176			157			P = 0.04
Vuorma 2003 (RAND-36)	1 year			9.2			6.3	No difference
Bodily pain								
Morgan 2000 (SF- 36)	6 months post	72	81 (22)	+6.0	88	77 (24)	+5.0	No difference
Kennedy 2002 (SF- 36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		6.5	159		6.2	No difference
Role emotional								

Table 5. General health outcomes (Continued)

Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		12.6	159		1.9	P = 0.01
Energy/vitality								
Kennedy 2002 (SF-36)	2 years	176			157			No difference
Vuorma 2003 (RAND-36)	1 year	156		8.9	159		8.8	No difference
SF-36 all dimensions								
Murray 2001b (SF-36)	9 months	93			94			No difference
Murray 2001a (SP-36)	9 months	54			48			No difference
Functional status								
Deyo 2000 (Roland Disability Questionnaire)	1 year	171	20.4	+5.4	173	20.9	+5.7	No difference
Health Utilities								
Murray 2001a (Euroqol EQ-5D)								No difference
Murray 2001b (Euroqol EQ-5D)								No difference
Depression								

Table 5. General health outcomes (Continued)

Davison 1997 (20-item Centre for Epidemiology Studies Depression Scale (CES-D))	5 to 6 weeks	30	29.8	-0.6	30	29.5	+1.3	No difference
Whelan 2004 (20-item CES-D)	1 week post DA	94	13.8 (1.0)		107	13.4 (1.1)		No difference
	6 months post DA	94	15.1 (1.1)		107	14.2 (1.2)		No difference
	12 months post DA	94	13.2 (1.3)		107	12.8 (1.2)		No difference

[Deyo 2000](#), using the previously validated Roland Disability Questionnaire ([Roland 1983](#)) to measure functional status in patients with back pain, found no difference between the detailed decision aid and simple decision aid groups.

In two studies measuring health utilities using the Euroqol EQ-5D ([Murray 2001a](#); [Murray 2001b](#)), there was no difference between the decision aid and usual care groups.

Condition-specific health outcomes

Seven studies (see [Table 6](#)) used various measures to assess condition-specific health outcomes. Six of these compared decision aids to usual care ([Barry 1997](#); [Bernstein 1998](#); [Morgan 2000](#); [Murray 2001a](#); [Murray 2001b](#); [Vuorma 2003](#)) and one compared a detailed decision aid to a simple decision aid ([Deyo 2000](#)). Outcomes included urinary symptoms ([Barry 1997](#); [Murray 2001a](#)), angina ([Bernstein 1998](#); [Morgan 2000](#)), back pain ([Deyo 2000](#)), menopausal symptoms ([Murray 2001b](#)), and menstrual symptoms ([Vuorma 2003](#)). Five of the 7 studies ([Bernstein 1998](#); [Morgan 2000](#); [Murray 2001a](#); [Murray 2001b](#); [Vuorma 2003](#)) found no significant effects on condition-specific health outcomes. [Deyo 2000](#) found no significant differences according to most measures except for back pain severity for which improvement was shown, one year later, in the decision aid group. [Barry 1997](#) showed an improvement in urinary symptoms in favour of the decision aid group, but it was not statistically significant.

Table 6. Condition-specific health outcomes

Study	Outcome	Scale Used	Timing	N Decision Aid	DA mean change	N Comparison	Comparison mean change	Notes
Barry 1997	Urinary symptoms	AUA Symptom Index (0 to 100)	3 months	104	-4.80% (1.74)	117	-1.40% (1.37)	No difference; trend toward DA
	Urinary symptoms	AUA	6 months	104	-3.66% (2.06)	117	-3.17% (1.77)	No difference
	Urinary symptoms	AUA	12 months	104	-2.51% (2.11)	117	-4.14% (1.66)	No difference; trend toward control
	Impact of symptoms	BPU Impact Index (0 to 100)	3 months	104	-6.58% (1.10)	117	-3.00% (1.05)	No difference; trend toward DA
	Impact of symptoms	BPU	6 months	104	-4.37% (1.32)	117	-3.89% (1.16)	No difference; trend toward DA
	Impact of symptoms	BPU	12 months	104	-5.53% (1.32)	117	-2.63% (1.32)	No difference; trend toward DA
Bernstein 1998	Satisfaction	Seattle Angina Questionnaire (SAQ) (0 to 100)	3 months	61	+6.2%	48	+10.5%	Control significantly more satisfied
	Angina stability	SAQ	3 months	61	+17.2%	48	+28.3%	No difference
	Angina frequency	SAQ	3 months	61	+5.5%	48	+15.3%	No difference
	Disease Perception	SAQ	3 months	61	+14.1%	48	+18.8%	No difference
	Physical Capacity	SAQ	3 months	61	-0.5%	48	+7.1%	No difference
Deyo 2000	% working		1 year	171	+17.3%	173	+18.3%	No difference

Table 6. Condition-specific health outcomes (Continued)

	% missed 1+ day work within past month		1 year	171	-38.4%	173	-35.2%	No difference
	Back pain severity		1 year	171	-22.4%	173	-22%	1 year scores: DA 27.6% significantly better than control 37.2%
	Leg pain severity		1 year	171	-42.1%	173	-43.9%	No difference
	Seeking compensation		1 year	171	-2.9%	173	-5.9%	No difference
	Satisfied with symptoms		1 year	171	+32.1%	173	+32.4%	No difference
Morgan 2000	No Angina	Canadian Cardiovascular Angina (CCVA)	6 months	72	+49%	88	+48%	No difference
	Class I Angina	CCVA	6 months	72	-1%	88	+6%	No difference
	Class II Angina	CCVA	6 months	72	-23%	88	-26%	No difference
	Class III Angina	CCVA	6 months	72	-26%	88	-28%	No difference
	Class IV Angina	CCVA	6 months	72	0%	88	0%	No difference
Murray 2001a	Urinary symptoms	AUA symptom Index (0 to 100)						No difference
Murray 2001b	Menopausal symptoms	MenQol						No difference

Table 6. Condition-specific health outcomes (Continued)

Vuorma 2003	Inconvenience due to menstrual bleeding	(5 to 25)	1 year	156	10.4	159	10.5	No difference
	Menstrual pain	(0 to 12)	1 year	156	4.7	159	4.6	No difference

Anxiety

Thirteen studies measured state anxiety using the previously validated 20-item State Anxiety Inventory (Spielberger 1970). Eleven of these studies (Bekker 2004; Davison 1997; Green 2004; Hunter 2005; Montgomery 2003; Murray 2001a; Murray 2001b; Vuorma 2003; Whelan 2003; Whelan 2004; Wong 2006) involved decision aid/usual care comparisons, and two (Goel 2001; vanRoosmalen 2004) involved detailed/simple decision aid comparisons (Table 7). None of these studies demonstrated significant differences in effects on people's state anxiety. The study by Johnson 2006 measured anxiety by response to a single seven-point Likert scaled question and found no significant difference between a group administered a decision board versus usual care (Table 7).

Table 7. Anxiety

Study	Timing	N Decision Aid	Mean DA (SD)	Change from Base-line	N Comparison	Mean Comparison (SD)	Change from Base-line	Notes
<i>State Anxiety Inventory: <30 days post-intervention</i>								
Goel 2001; breast cancer surgery	1 to 3 days post DA	74	51.2 (14.2)	-0.7	43	50.7 (14.8)	-0.1	No difference
Montgomery 2003; hypertension	immediately post DA	44	35.45 (10.52)		50	37.67 (13.92)		No difference
Whelan 2004; breast cancer surgery	7 days post DA	94	42.3 (1.3)		107	41.9 (1.3)		No difference

Table 7. Anxiety (Continued)

Whelan 2003; breast chemotherapy	7 days post DA	82	45.6	+2.2	93	47.4	+0.8	No difference
Green 2004; breast cancer screening (low risk group)	Immediately post	56	29	-4	61	30	-3	P = 0.04 (for difference in change score)
Green 2004; breast cancer screening (high risk group)	Immediately post	50	30	-3	44	33	-5	P = 0.04 (for difference in change score)
Hunter 2005; pre-natal screening	Immediately post	116	45.50 (9.69)	-1.17	126	47.98 (10.14)	-0.37	No difference
Wong 2006; pregnancy termination	Immediately post	154	54 (15.8)		159	54 (16.1)		
Bekker 2004; pre-natal screening	Immediately post	50	58.9 (16.6)		56	61.2 (13.7)		No difference
State Anxiety Inventory: 1 month post-intervention								
Davison 1997; prostate cancer treatment	5 to 6 weeks post DA	30	35.5	-9.0	30	34.5	-2.5	No difference
vanRoosmalen 2004	1 month post DA	43	35.4 (11.7)		43	37.4 (10.7)		No difference
Bekker 2004; pre-natal screening	1 month post DA	29	35.3 (12.5)		39	34.7(14.8)		No difference

Table 7. Anxiety (Continued)

<i>State Anxiety Inventory: 3 months post-intervention</i>								
Murray 2001a; BPH	3 months post DA	55	36.36 (14.99)	+2.4	48	32.08 (9.836)	+0.7	No difference
Murray 2001b; HRT	3 months post DA	93	38.42 (10.83)	-0.5	95	40.53 (12.96)	+1.8	No difference
Vuorma 2003; menorrhagia treatment	3 months post DA	184	37.1	+1.0	179	35.9	-1.0	No difference
Whelan 2003; breast chemotherapy	3 months post DA	82	36.0		93	37.8		No difference
<i>State Anxiety Inventory: 6 months post-intervention</i>								
Goel 2001; breast cancer surgery	6 months post DA	59	36.6 (12.9)	-15.3	39	34.3 (11.6)	-16.5	No difference
Whelan 2004; breast cancer surgery	6 months post DA	94	39.3 (1.3)		107	38.9 (1.6)		No difference
Whelan 2003; breast chemotherapy	6 months post DA	82	38.2		93	38.2		No difference
<i>State Anxiety Inventory: 12 months post-intervention</i>								
Whelan 2004; breast cancer surgery	12 months post DA	94	37.5 (1.4)		107	36.6 (1.5)		No difference
Whelan 2003; breast chemotherapy	12 months post DA	82	39.2		93	40.2		No difference
<i>Trait Anxiety</i>								

Table 7. Anxiety (Continued)

Davison 1997 ; prostate cancer treat- ment	5 to 6 weeks post DA	30	34.5	-0.5	30	33.0	+2.5	No difference
<i>Single question 7-point Likert scale</i>								
Johnson 2006 ; endodontic treatment	Immedi- ately post	32	3.2 (1.7)		35	3.8 (2.1)		P = 0.27

Depression

[Davison 1997](#) found no significant difference between groups for depression at 5 to 6 weeks post-intervention, measured on the previously validated 20-item Centre for Epidemiologic Studies Depression Scale ([Radloff 1977](#)); nor did [Whelan 2004](#) at 1 week, 6 months and 12 months post-intervention ([Table 5](#)).

Regret

One study ([Goel 2001](#)), comparing a simple decision aid to a detailed decision aid, measured decisional regret on the 5-item Decisional Regret scale ([O'Connor 2001a](#)). There were no significant differences between the groups ([Table 8](#)).

Table 8. Decisional regret

Author	Item	Decision Aid (n = 63)	Control (n = 44)	Notes
Goel 2001	Right decision	58 (92.06%)	42 (95.45%)	No difference
	Regret choice	8 (12.70%)	5 (11.36%)	No difference
	Would make same choice	54 (85.71%)	40 (90.91%)	No difference
	Choice did me harm	7 (11.11%)	3 (6.82%)	No difference
	Decision was wise	54 (85.71%)	41 (93.18%)	No difference

Confidence

Four trials measured the effect of decision aids on confidence levels (Table 3). One trial measured participants' confidence related to personal ability to understand the outcomes of HRT, make a decision, and engage in discussion with their practitioner (McBride 2002). The second trial measured confidence related to actively participating in discussions with one's practitioner (Rothert 1997). The other two trials measured participants' perceived ability to make an informed choice regarding PSA screening (Gattellari 2003; Gattellari 2005). In McBride 2002, women who used the decision aid had higher confidence scores at one month post-intervention (78% versus 70%) than those who received usual care. This difference was statistically significant. Furthermore, the women in the decision aid group who were confident were more likely to remain confident in their decision at the nine month follow-up. Rothert 1997 found no difference in women's level of confidence when comparing more detailed to simple decision aids. Gattellari 2003 found that men who received a decision aid regarding PSA screening were significantly more likely to indicate that they were more able to make an informed decision than men who received general information. However, Gattellari 2005 found no difference between groups.

Healthcare system effects

Cost and resource use

Four trials evaluated the impact of decision aids compared to usual care on cost and resource use (Kennedy 2002; Murray 2001a; Murray 2001b; Vuorma 2003). Both trials by Murray involved a cost-minimization economic analysis from the perspective of the healthcare system decision-maker, with less than 4% of resource use items being replaced by conditional means due to missing data. There was no significant difference between the groups in terms of health service resource use. There was a difference in costs, when expensive interactive videodisc equipment was considered in the analysis. However, if one substituted low cost internet access to the decision aids, there was no significant difference in the cost. The cost analysis in the Kennedy 2002 trial was also conducted from the healthcare system perspective using 1999 to 2000 US dollars and calculated over 2 years. The decision aid with nurse coaching had the lowest mean cost (\$1566) compared to decision aid alone (\$2026) or usual care (\$2751).

In the Vuorma 2003 trial, despite the statistically insignificant trend for lower diagnostic procedures (55 versus 89, $P = 0.07$) and lower uterine saving surgery procedures (16 versus 26, $P = 0.08$) in the intervention group, there was no difference between the intervention and control group when treatment cost and productivity losses were analysed at the one year follow-up.

Consultation length

Three trials (Bekker 2004; Green 2004; Whelan 2003) evaluated the effect of a decision aid on consultation length, with varied results. Bekker 2004 found that, on average, consultation times were about 6 minutes longer for women receiving decision analysis versus women receiving routine consultation for prenatal diagnostic testing. Green 2004 found that the average consultation length was 8 minutes shorter for women who received a decision aid prior to genetic counselling for breast cancer screening compared to women who received routine genetic counselling. Both of these results were statistically significant. Whelan 2003 did not find a statistically significant difference in consultation length for women considering adjuvant therapy for breast cancer who received a decision board (68 minutes) versus standard counselling (66 minutes; $P = 0.5$). (See Table 3).

Two trials evaluated the effect of decision aids on the quality of the consultation session. Green 2004 evaluated both the practitioner's and the patient's evaluation of consultation effectiveness with a single seven-point Likert question. There was no difference between treatment and control groups with regard to both the physician and the patient evaluations. Bekker 2004 evaluated the perceived usefulness and directiveness of the consultation and found no difference between intervention and control groups on either of these outcomes.

None of the studies examined the effect of decision aids on litigation. As well, preference-linked health outcomes—that is, whether the patients experienced the outcomes they preferred and avoided the outcomes they did not prefer—were not evaluated.

Post hoc analysis

Effects of study quality

To examine the potential bias from including trials of low methodological quality, the 13 trials (Barry 1997; Deschamps 2004; Green 2001a; Herrera 1983; Lerman 1997; McBride 2002; O'Connor 1998a; Oakley 2006; Phillips 1995; Rothert 1997; Schapira 2000; Street 1995; Wolf 2000) with Jadad scores of 0 or 1 were excluded from the analysis. Overall, the results remained the same. There was a significant improvement in knowledge scores for the comparison of patient decision aids to usual care controls (MD 13.9%; 95% CI 10.2 to 17.6) and for the comparison of detailed to simpler patient decision aids (MD 5.5%; 95% CI 2.4 to 8.6). The proportion of patients having accurate risk perceptions was greater for patients receiving patient decision aids with information on outcome probabilities (RR 2.0; 95% CI 1.4 to 2.8). However, we no longer had pooled results for the comparison of detailed versus simple decision aids for the following outcomes: uptake of major elective surgery, and uptake of hormone replacement therapy.

Heterogeneity

There was statistically significant heterogeneity when patient decision aids were compared to usual care for four of the IPDAS effectiveness criteria: knowledge test scores; realistic risk percep-

tions; feeling uninformed; and feeling unclear regarding personal values. It should be noted that the heterogeneity of the effect was not in the direction but in the size.

When we explored the potential factors contributing to heterogeneity (Table 9), we found that none of the factors eliminated heterogeneity for the outcomes of knowledge scores. When grouped into treatment and screening decisions, the MD for knowledge scores was slightly higher for the treatment group (16.5% versus 13.1%), but there was still statistically significant heterogeneity. For the outcomes of accurate risk perceptions, heterogeneity was not significant when we removed three studies with lower accurate risk perception scores in the usual control group ($P = 0.3$) (Gattellari 2003; Man-Son-Hing 1999; McAlister 2005). For the outcome of feeling uninformed, heterogeneity was no longer significant with: a) removal of three studies with higher uninformed scores in the usual care control group ($P = 0.11$); b) inclusion of only audio booklet/pamphlet decision aids ($P = 0.06$); and c) removal of an outlier (Montgomery 2003) ($P = 0.06$). None of the factors eliminated heterogeneity for the outcomes of unclear values scores.

Table 9. Heterogeneity

Outcome	Overall Effect	Treatment Decision	Screening Decision	Video/Computer DA	Audio/Pamphlet DA	Base Control	Risk	Removal of Outliers*
Knowledge	15.2 (11.7 to 18.7)	16.5 (11.9 to 21.2)	13.1 (7.7 to 18.5)	21.3 (16.3 to 26.2)	11.9 (8.3 to 15.6)	15.5 (11.3 to 19.8)		17.3 (13.6 to 20.9) (* Bekker 2004, Gattellari 2003, Johnson 2006)
Accurate Risk Perceptions	1.6 (1.4 to 1.9)	1.6 (1.4 to 1.9)	1.6 (1.1 to 2.3)	No data	1.6 (1.4 to 1.9)	1.3 (1.2 to 1.5) ($P = 0.3$)		1.5 (1.3 to 1.7) (* Gattellari 2003)
Uninformed subscale of the DCS	-8.4 (-11.9 to -4.8)	-9.4 (-13.3 to -5.5)	-3.5 (-12.9 to 5.8)	-12.6 (-19.5 to -5.8)	-4.9 (-7.6 to -2.3) ($P = 0.06$)	-5.4 (-7.7 to -3.2) ($P = 0.11$)		-6.2 (-8.4 to -4.1) ($P = 0.06$) (* Montgomery 2003)
Unclear values subscale of the DCS	-6.3 (-10.0 to -2.7)	-6.0 (-9.8 to -2.3)	Insufficient data	-8.0 (-15.1 to -1.0)	-4.5 (-8.4 to -0.6)	-3.6 (-6.8 to -0.5)		-4.0 (-6.7 to -1.3) (* Montgomery 2003)

DISCUSSION

The addition of 25 trials in this updated review has confirmed many of the observations of the previous review (O'Connor 2003b). Decision aids do a better job than usual care interventions in improving people's knowledge regarding options, reducing their decisional conflict related to feeling uninformed and unclear about personal values, decreasing the proportion of people remaining undecided, and stimulating people to take a more active role in decision making. Compared to simpler versions, detailed decision aids improved knowledge only marginally, but had other benefits. For example, if probabilities of outcomes were included, there were more accurate risk perceptions, especially if they were presented quantitatively. There was also some evidence of better congruence between values and chosen option.

The impact of decision aids on increasing or decreasing preferences for particular options continues to be variable. As noted previously, most trials appear to dampen women's preferences for menopausal hormones; moreover, people's enthusiasm for major elective surgery is decreased in favour of more conservative options. In this review, the preference for PSA testing was also decreased with exposure to decision aids.

Decision aids do not better than alternative interventions on people's satisfaction with decision making, anxiety, or health outcomes such as general quality of life, or condition-specific quality of life. There continue to be too few studies to determine the effects of decision aids on persistence with the chosen therapy, costs, or resource use.

Study limitations

Study quality ratings of all trials included in the review were low because they all lost 2 points for lack of blinding. While not an *a priori* exclusion criterion for this review, in the future we may consider using study quality ratings for the selection of included trials through conducting a Risk of Bias assessment. The conclusions of this review are limited by: a) inadequate power to detect important differences in effectiveness in subgroups; and b) the wide variability in the decision contexts, the elements within the patient decision aids, the type of comparison interventions, the targeted outcomes, and the evaluation procedures. The small number of studies for most outcomes did not allow for analysis of publication bias due to failure to publish negative studies. Moreover, there may have been publication bias due to failure to report all negative findings in a published study. Lastly, several of the outcomes demonstrated statistically significant heterogeneity. It reflects differences across clinically diverse studies; therefore, the pooled effect size and CI should be interpreted as a range across conditions, which may not be applicable to a specific condition.

Main effects of decision aids

The largest and most consistent benefits of decision aids, relative to usual care, are better knowledge of options and outcomes and more accurate perceptions of outcome probabilities. These observations are clinically important for two reasons. First, the usual care group's knowledge and understanding of probable outcomes were less than adequate for informed decision making. Second, participants often changed from their initial decision once their knowledge and risk perceptions improved. Taken together, these effects on knowledge and risk perceptions suggest that current 'usual care' may not be good enough when informing people about these complex, value-laden decisions. People need to comprehend the options and probable outcomes in order to consider and communicate to their practitioners the personal value they place on the benefits versus the harms.

Decision aids compared to usual care also help people feel more comfortable with their choices. This is revealed by the reduced scores for the decisional conflict subscales. People who use decision aids generally feel more informed about options and clearer regarding their personal values.

Compared to usual care strategies, decision aids improve individuals' involvement in decision making. This observation suggests that the IPDAS criterion of helping patients participate 'in ways that they prefer', needs to be assessed after a patient has adequate information about what involvement means. People may have a mistaken preference for passivity because they believe that the best choice relies on the expertise of the clinician (which option is medically reasonable?) rather than the opinions of the person who will experience the outcomes (which outcomes matter most to me?).

Variable effects of decision aids

There may be several reasons for the variable impact of decision aids on actual choices. First, most studies were underpowered to detect important differences in actual choices. Second, in the five studies reporting actual choices at baseline and post decision aid, some options may have been underused and others overused, relative to the actual choices individuals would make if they were more fully informed. Under these circumstances, one could expect to observe directional effects on actual choices once people become better informed and more involved in decision making. Examples of relatively underused options at baseline were colon cancer screening and hepatitis B vaccination. Another illustration lies in the non-significant 5-fold increase in rates of surgery in the UK trial. At the time there was a shortage of urologists and low referrals for benign prostatic hyperplasia. This situation may have resulted in under-use of an option, which was corrected with exposure to a decision aid. In contrast, the other surgical decision aid trials had higher uptake rates in the control group. The procedure may have been over-used due to people's inflated perceptions of the probabilities of benefits, lack of appreciation of the probabil-

ities of harms, and lack of awareness of alternatives. Exposure to the decision aid reduced preferences for surgery in favour of more conservative alternatives.

Limited effects of decision aids

The limited effects of decision aids on reported satisfaction with the decision making process and with the actual choice made may indicate that decision aids have a limited effect on satisfaction. The null effects may also be due to measurement insensitivity. This is especially likely when satisfaction with usual care is already quite high and when choices are inherently difficult to make because of competing benefits and harms. As well, satisfaction could be more strongly affected by the relationship with the practitioner than the decision aid. Furthermore, once the decision is made, people may find it psychologically more comforting to say that they are satisfied rather than entertain doubts about what they have chosen (Gruppen 1994).

It is not surprising that decision aids had limited effects on health outcomes. The reason for using a decision aid is that there is no option with a clear health outcome advantage. If health outcomes are used in future investigations of decision aids, the key question to pose is: Do patients experience the health outcomes they prefer and avoid the outcomes to which they are averse?

The small differences in knowledge and decisional conflict scores between detailed and simpler versions of decision aids are likely due to the overlapping information presented in the two interventions. This raises questions about the minimum information needed for the decision aid to be effective. It was clear from Goel 2001 that, for their population of women with a strong prior preference for lumpectomy, a simple pamphlet describing options and outcomes of mastectomy versus lumpectomy was comparable to a detailed audio-workbook. A post-hoc analysis, however, revealed that women who were uncertain about their choice at baseline or leaning toward mastectomy, appeared to benefit more from the detailed aid. There is a need to establish the 'essential ingredients' in decision aids and to identify the people who are most likely to benefit from detailed versions. To do this, it is recommended that future trials assess baseline predispositions toward options (strongly leaning toward option A, unsure, strongly leaning toward option B) and stage of decision making (not thinking about options, actively weighing options, close to selecting an option, have made a choice but willing to re-consider, have made a choice and unwilling to reconsider). As the body of available research grows, it will become easier and more important to assess the usefulness of different components of decision support for different clinical contexts, decision problems, and groups of people.

Unknown effects of decision aids

The effects of patient decision aids on other outcomes (consultation length, adherence) are inconclusive. For consultation length,

this variable is likely dependent on the type of practice and more studies in the same context are needed. The adherence results are difficult to interpret due to incomplete data, varying length of follow-up (4 to 36 months), and small sample size ($n = 33$ in one study). Moreover, studies such as Man-Son-Hing 1999 had very little variation in choice (over 90% of long term aspirin users decided to stay on aspirin). It would be important to examine adherence: a) separating those choosing to change versus remain with status quo; and b) in the early phase, when presumably the issue is decisional (e.g. filling the prescription; picking up the prescription; refilling the prescription) rather than management of side effects.

AUTHORS' CONCLUSIONS

Implications for practice

The positive effects of decision aids in facilitating active participation and informed decision making may provide sufficient evidence for using them in clinical practice. However, several conditions may be necessary for successful implementation: a) good quality decision aids to meet the needs of the population; b) practitioners willing to use decision aids in their practice; c) effective systems for delivering decision support; and d) practitioners and healthcare consumers who are skilled in shared decision making. Although some strides have been made in achieving these conditions (O'Connor 2007), the use of patient decision aids will not occur without adequate attention to the barriers to implementation (Gravel 2006).

Implications for research

Studies are needed to deepen our understanding of: interactions between patient decision aid use and the patterns of patient-practitioner communication; format issues such as web-based delivery of patient decision aids; timing issues regarding most effective use of decision aids before, during or after a consultation; and downstream effects on adherence to a chosen option, decisional regret, cost, resource use, and litigation rates.

More studies are needed to evaluate the effects of patient decision aids on congruence between values and chosen options. Moreover the methods for quantifying value congruence should be explored.

With the addition of more trials to the systematic review, it may be possible to tease out the reasons for heterogeneity of results including variability in: a) study quality; b) comparison intervention; c) elements within patient decision aids; d) decision type; and e) format of decision aid (e.g., video, Internet, booklet). The degree of detail in patient decision aids that is required for positive effects on IPDAS criteria should also be explored.

Research is needed to ensure that decision aids are accessible to people with low literacy. We also need to examine ways of facilitating the introduction and uptake of patient decision aids in various clinical settings, and to explore different practice models supporting their implementation.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Auvinen 2004

Methods	Pamphlet vs usual care	
Participants	103 + 100 men newly diagnosed with prostate cancer	
Interventions	DA: pamphlet patient decision aid created for trial on options' outcomes, outcome probability COMPARE: standard care by clinical guideline	
Outcomes	Uptake of options, participation in decision making	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Barry 1997

Methods	Interactive video disc vs general information	
Participants	104 + 123 patients considering benign prostatic hyperplasia treatment	
Interventions	DA: interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: general information on the clinical problem	
Outcomes	uptake of option; knowledge; satisfaction with DM process; satisfaction with decision; interest in DM; general health outcomes; condition specific health outcomes	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Bekker 2004

Methods	Decision analysis + routine consultation vs routine consultation	
Participants	59 + 58 pregnant women who have received a maternal serum screening positive test result for Down syndrome	
Interventions	DA: decision analysis plus routine consultation on options' outcomes, outcome probability, values clarification COMPARE: routine consultation on options' outcomes, outcome probability	
Outcomes	uptake of option; knowledge; decisional conflict; anxiety; informed decision making; satisfaction with consultation; consultation length	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Bernstein 1998

Methods	Video vs usual care	
Participants	61 + 48 patients with coronary artery disease considering revascularization surgery	
Interventions	DA: video on options' outcomes, clinical problem, others' opinion COMPARE: usual care	
Outcomes	uptake of option, knowledge, satisfaction with care, satisfaction with decision making process, general health outcomes, condition specific health outcomes	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Clancy 1988

Methods	Pamphlet + personal decision analysis vs usual care	
Participants	753 + 264 + 263 Health physicians considering Hep B vaccine	

Clancy 1988 (Continued)

Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching COMPARE: usual care
Outcomes	uptake of option
Notes	Quality = 2 r=2 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Davison 1997

Methods	Written + audiotaped consultation vs pamphlets
Participants	30 + 30 men with prostate cancer considering treatment
Interventions	DA: written + audiotape consultation of options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: general information pamphlets on clinical problem
Outcomes	role in decision making, anxiety, depression
Notes	Quality = 2 r=2 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Deschamps 2004

Methods	Audiotape booklet vs pharmacist consultation
Participants	67 + 61 women considering hormone replacement therapy
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, values clarification, others' opinions, guidance/coaching COMPARE: 40-minute pharmacist consultation on options' outcomes, outcome probability

Deschamps 2004 (Continued)

Outcomes	preferred option, decisional conflict, role in decision making, satisfaction with preparation for decision making, satisfaction with decision, adherence	
Notes	Quality = 1 r=1 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Deyo 2000

Methods	Interactive videodisc vs pamphlet	
Participants	190 + 203 adults with herniated disc or spinal stenosis considering back surgery	
Interventions	DA: interactive videodisc on options' outcomes, clinical problem, outcome probability, other's opinions COMPARE: simple DA pamphlet with clinical problem, options outcomes.	
Outcomes	uptake of option, satisfaction with DM process, satisfaction with care, condition specific health outcomes	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Dodin 2001

Methods	Audiotape booklet vs pamphlet	
Participants	52 + 49 women considering hormone replacement therapy	
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: simple decision aid pamphlet with options' outcomes, clinical problem	
Outcomes	preferred option, knowledge, decisional conflict, realistic expectations, congruence between values and choice	
Notes	Quality = 2 r=1 b=0 f=1	

Dodin 2001 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Dolan 2002

Methods	Computer + pamphlet vs pamphlet (usual care)	
Participants	50 + 47 average risk for colorectal cancer considering screening	
Interventions	DA: computer with analytic hierarchy process on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching COMPARE: usual care with information on options, clinical problem.	
Outcomes	uptake of option, decisional conflict, role in decision making	
Notes	Quality = 3 r=2 b=0 f=1	

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Dunn 1998

Methods	Video + pamphlet vs pamphlet	
Participants	143 + 144 parents of infants considering polio vaccine schedules	
Interventions	DA: video + pamphlet on options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: general information on clinical problem	
Outcomes	knowledge	
Notes	Quality = 2 r=1 b=0 f=1	

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Frosch 2003

Methods	Video vs website	
Participants	112 + 114 men considering PSA testing	
Interventions	DA: video on options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: Internet presentation mirroring content of video decision aid	
Outcomes	preferred option, knowledge	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Gattellari 2003

Methods	Decision aid vs general information leaflet	
Participants	126 + 122 men considering PSA testing	
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, values clarification COMPARE: brief information on screening test and chances of false-positive results	
Outcomes	preferred option, knowledge, decisional conflict, realistic expectation of outcomes, perceived ability to make an informed choice	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Gattellari 2005

Methods	Booklet decision aid vs video decision aid vs general information leaflet	
Participants	140 + 141 + 140 men considering PSA testing	
Interventions	DA: pamphlet on options' outcomes, clinical problem, outcome probability, values clarification COMPARE: video on clinical problem, outcome probability, others' opinion	

Gattellari 2005 (Continued)

	COMPARE: brief information on screening test and chances of false-positive results	
Outcomes	preferred option, knowledge, decisional conflict, perceived ability to make an informed choice	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Goel 2001

Methods	Audiotape booklet vs pamphlet	
Participants	86 + 50 women considering surgery for breast cancer	
Interventions	DA: audiotape + booklet on options' outcomes, clinical problem, outcome probability, values clarification, other's opinions, coaching/guidance COMPARE: simple DA pamphlet with clinical problem, options outcomes	
Outcomes	knowledge, decisional conflict, decisional regret, anxiety	
Notes	Quality =3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Green 2001a

Methods	Computer + counselling vs counselling vs usual care	
Participants	29 + 14 women with a first degree relative with breast cancer interested in learning about genetic testing	
Interventions	DA: CD-ROM plus counselling on options' outcomes, clinical problem, others' opinions COMPARE: Usual care	
Outcomes	knowledge, preferred options	
Notes	Quality = 1 r=1 b=0 f=0	

Green 2001a (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Green 2004

Methods	Computer-based decision aid plus genetic counselling vs usual care
Participants	106 + 105 women with first degree relative with breast cancer considering genetic testing
Interventions	DA: CD-ROM plus counselling on options' outcomes, clinical problem, others' opinions COMPARE: genetic counselling
Outcomes	preferred option, knowledge, decisional conflict, satisfaction with decision, anxiety, counsellor/participant rating of effectiveness of counselling session, consultation length
Notes	Quality = 3 r=2 b=0 f=1

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Herrera 1983

Methods	Pamphlet + discussion vs usual care
Participants	56 + 47 parent(s) considering circumcision for male newborns
Interventions	DA: pamphlet + discussion on options' outcomes, clinical problem, outcome probability, others' opinions, guidance/coaching COMPARE: usual care
Outcomes	uptake of option
Notes	Quality = 0 r=0 b=0 f=0

<i>Risk of bias</i>		
Item	Authors' judgement	Description

Herrera 1983 (Continued)

Allocation concealment?	No	C - Inadequate
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Hunter 2005

Methods	Patient decision aid with option to speak to genetic counsellor vs individual genetic counselling vs group counselling
Participants	116 + 126 + 110 women of advanced maternal age considering prenatal diagnostic testing
Interventions	DA: audiotape workbook on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: individual counselling session on options' outcomes, outcome probability, values clarification COMPARE: group counselling session on options' outcomes, outcome probability, others' opinions
Outcomes	uptake of option, knowledge, decisional conflict, satisfaction with decision making process, anxiety
Notes	Quality = 2 r=1 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Johnson 2006

Methods	Decision board vs usual care
Participants	32 + 35 patients considering endodontic treatment options
Interventions	DA: decision board on options' outcomes, clinical problem, outcome probability COMPARE: usual care
Outcomes	knowledge, satisfaction, anxiety
Notes	Quality = 3 r=2 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Kennedy 2002

Methods	Video + booklet + coaching vs video + pamphlet vs usual care	
Participants	215 + 206 + 204 women considering treatment for menorrhagia	
Interventions	DA: video + booklet on options' outcomes, clinical problem, outcome probabilities, values clarification, others' opinions, guidance/coaching COACHING: ~20 minute coaching, in making a decision, with a registered nurse prior to see physician COMPARE: usual care	
Outcomes	uptake of option, satisfaction, general quality of life, menorrhagia severity, cost effectiveness	
Notes	Quality = 3 r=2 b=0 f=1	
Risk of bias		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Lalonde 2006

Methods	Booklet and personal worksheet + pharmacist consultation vs personal risk profile + pharmacist consultation	
Participants	13 + 13 patients considering lifestyle changes and drug therapy to improve cardiovascular health	
Interventions	DA: booklet and worksheet on options' outcomes, clinical problem, outcome probability, values clarification, others' opinion, guidance/coaching COMPARE: personal risk profile with clinical problem, outcome probabilities	
Outcomes	knowledge, risk perception, decisional conflict, satisfaction with decision making process	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Laupacis 2006

Methods	Decision aid vs usual care	
Participants	60 + 60 patients undergoing elective open heart surgery considering pre-operative autologous blood donation	

Laupacis 2006 (Continued)

Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: usual care	
Outcomes	uptake of option, knowledge, decisional conflict, satisfaction with decision making process, satisfaction with decision, realistic expectations	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Legare 2003

Methods	Decision aid vs general information pamphlet	
Participants	97 + 87 post-menopausal women considering hormone replacement therapy	
Interventions	DA: audiotape, booklet and worksheet on options' outcomes, clinical problem, outcome probabilities, values clarification, others' opinions, guidance/coaching COMPARE: general information pamphlet on risks, benefits and side-effects of HRT	
Outcomes	decisional conflict, satisfaction with decision making process, agreement between physicians' and patients' decisional conflict	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Lerman 1997

Methods	Discussion + counselling vs waiting list control	
Participants	122 + 114 + 164 women considering BRCA1 gene testing	
Interventions	DA: Education and counselling on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: no intervention	

Lerman 1997 (Continued)

Outcomes	preferred option, knowledge, realistic expectations, perceived personal risk / benefits / limitations, agreement between values and choice	
Notes	Quality =1 r=1 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Leung 2004

Methods	Interactive multimedia decision aid vs video and leaflet	
Participants	100 + 101 women considering prenatal diagnostic testing	
Interventions	DA: interactive multimedia decision aid on options' outcomes, clinical problem, outcome probability, implicit values clarification, guidance/coaching COMPARE: video and leaflet on options' outcomes, clinical problem, outcome probability	
Outcomes	Preferred option, proportion remaining undecided, uptake of option	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Man-Son-Hing 1999

Methods	Audiotape booklet vs usual care	
Participants	139 + 148 patients on atrial fibrillation trial considering continuing on aspirin vs change to Warfarin	
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: usual care	
Outcomes	uptake of options, help with making a decision, knowledge, realistic expectations, decisional conflict, satisfaction with decision making process, role in decision making, adherence	

Man-Son-Hing 1999 (Continued)

Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

McAlister 2005

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McBride 2002

Methods	Pamphlet vs usual care
Participants	289 + 292 peri-menopausal women considering hormone replacement therapy
Interventions	DA: options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: delayed intervention
Outcomes	realistic expectations, satisfaction with decision, confidence with knowledge & making/discussing decision
Notes	Quality = 1 r=1 b=0 f=0
Risk of bias	

McBride 2002 (Continued)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Miller 2005

Methods	Enhanced educational intervention vs standard care
Participants	279 women considering BRCA1 BRCA2 gene testing
Interventions	DA: educational intervention on options' outcomes, clinical condition, personal family cancer history COMPARE: provision of general information about cancer risk
Outcomes	Preferred option, knowledge, perceived risk, satisfaction
Notes	Quality = 2 r=2 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Montgomery 2003

Methods	Decision analysis + information video and leaflet vs decision analysis vs information video and leaflet vs usual care
Participants	51 + 52 + 55 + 59 newly diagnosed hypertensive patients considering drug therapy for blood pressure
Interventions	DA: Decision analysis plus information video and leaflet on options' outcomes, clinical problem, outcome probability, values clarification COMPARE: Decision analysis on options' outcomes, outcome probability, values clarification COMPARE: Video and leaflet on options' outcomes, clinical problem COMPARE: usual care
Outcomes	uptake of option, knowledge, decisional conflict, anxiety
Notes	Quality = 3 r=2 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
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Montgomery 2003 (Continued)

Allocation concealment?	Yes	A - Adequate
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Morgan 2000

Methods	Interactive videodisc vs usual care
Participants	120 + 120 patients with Ischemic heart disease considering revascularization surgery
Interventions	DA: interactive videodisc on options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: usual care
Outcomes	uptake of option, knowledge
Notes	Quality = 3 r=2 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Murray 2001a

Methods	Interactive videodisc versus usual care
Participants	57 + 55 men considering treatment for benign prostatic hypertrophy
Interventions	DA: interactive videodisc on options, outcomes, clinical problem, outcome probability, others' opinions COMPARE: usual care
Outcomes	uptake of option, decisional conflict, role in decision making, prostate symptoms, costs, anxiety, general health status, utility
Notes	Quality = 3 r=2 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Murray 2001b

Methods	Interactive videodisc versus usual care	
Participants	102 + 102 women considering hormone replacement therapy	
Interventions	DA: interactive videodisc on options outcomes, clinical problem, outcome probability, other's opinion COMPARE: usual care	
Outcomes	preferred option, help with making a decision, decisional conflict, role in decision making anxiety, menopausal symptoms, costs, utility, general health status	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Myers 2005a

Methods	Booklet + education session vs booklet	
Participants	121 + 121 African-American men considering prostate cancer screening	
Interventions	DA: information booklet on clinical problem, options' outcomes + decision education session with values clarification, guidance/coaching COMPARE: information booklet on clinical problem, options' outcomes	
Outcomes	uptake of option	
Notes	Quality = 2 r=1 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

O'Connor 1999a

Methods	Audiotape booklet with values clarification vs audiotape booklet	
Participants	101 + 100 women considering long term hormone therapy	

O'Connor 1999a (Continued)

Interventions	DA: audiotape booklet on options outcomes, clinical problem, outcome probabilities, values clarification, others' opinion, guidance/coaching COMPARE: options outcomes, clinical problem, outcome probabilities, guidance/coaching.	
Outcomes	decisional conflict, congruence with values	
Notes	Quality = 3 r = 2, b=0, f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

O'Connor 1998a

Methods	Audiotape booklet vs pamphlet	
Participants	81 + 84 women considering long term hormone therapy	
Interventions	DA: audiotape booklet on options outcomes, clinical problem, outcome probability, values clarification, others' opinion, guidance/coaching COMPARE: simple DA pamphlet.	
Outcomes	preferred option, knowledge, decisional conflict, realistic expectations	
Notes	Quality = 1 r=1 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Oakley 2006

Methods	Decision aid vs usual care	
Participants	16 + 17 postmenopausal women with osteoporosis considering treatment options to prevent further bone loss	
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: usual care	

Oakley 2006 (Continued)

Outcomes	satisfaction with information, decisional conflict (intervention group only), improvement in adherence	
Notes	Quality = 1 r=1 b=0 b=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Partin 2004

Methods	Video vs pamphlet vs usual care	
Participants	384 + 384 + 384 men considering PSA testing	
Interventions	DA: FIMDM video on options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: pamphlet on options' outcomes, clinical problem, outcome probability COMPARE: usual care	
Outcomes	preferred option, help with making a decision, knowledge, decisional conflict	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Phillips 1995

Methods	video imaging + standard case presentation vs usual care	
Participants	37 + 37 patients considering dental orthognathic surgery	
Interventions	DA: video imaging of facial reconstruction including options outcomes, clinical problem, guidance/coaching COMPARE: usual care	
Outcomes	preferred option, expectations	
Notes	Quality = 0 r=0 b=0 f=0	

Phillips 1995 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Pignone 2000

Methods	Video vs usual care	
Participants	125 + 124 adults considering colon cancer screening	
Interventions	DA: video of options' outcomes, clinical problem, others' opinion COMPARE: video on car safety	
Outcomes	uptake of options	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Rostom 2002

Methods	Computer program vs audiotape booklet	
Participants	25 + 26 women considering hormone replacement therapy	
Interventions	DA: audiotape booklet on options' outcomes, clinical problem, outcome probabilities, values clarification, others' opinions, guidance/coaching COMPARE: computer version of same information with feedback to reinforce and correct participant knowledge	
Outcomes	knowledge, realistic expectations, satisfaction with decision aid	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description

Rostom 2002 (Continued)

Allocation concealment?	Yes	A - Adequate
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Rothert 1997

Methods	Lecture + personal decision exercise vs pamphlet
Participants	83 + 89 peri-menopausal women considering hormone replacement therapy
Interventions	DA: lecture with personal decision exercise on options' outcomes, clinical problem, outcome probability, values clarification, others' opinions, guidance/coaching COMPARE: simple DA pamphlet with clinical problem, options' outcomes
Outcomes	knowledge, decisional conflict, satisfaction with decision, satisfaction with provider, self-efficacy, adherence, likelihood to take HRT, consistency with values
Notes	Quality = 1 r=1 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Schapira 2000

Methods	Booklet vs pamphlet
Participants	122 + 135 men considering PSA testing
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability COMPARE: simple DA pamphlet with clinical problem, options' outcomes
Outcomes	uptake of option, knowledge, realistic expectations
Notes	Quality = 1 r=1 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Schwartz 2001

Methods	Booklet vs general information on breast cancer	
Participants	181 + 190 Ashkenazi Jewish women considering genetic testing	
Interventions	DA: 16-page booklet on genetic testing with options' outcomes, clinical problem COMPARE: general information on breast cancer	
Outcomes	preferred option, knowledge, realistic expectations	
Notes	Quality = 2 r=2 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Shorten 2005

Shroben 2005

Methods	decision aid booklet vs usual care	
Participants	85 + 84 pregnant women who have experienced previous cesarean section considering birthing options	
Interventions	DA: decision aid booklet on options' outcomes, clinical problem, outcome probabilities, values clarification, coaching/guidance COMPARE: usual care	
Outcomes	preferred option, help with making a decision, knowledge, decisional conflict	
Notes	Quality = 2 r=2 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Street 1995

Methods	Interactive multimedia vs pamphlet	
Participants	30 + 30 women considering breast cancer surgery	
Interventions	DA: interactive multimedia on options' outcomes, clinical problem, others' opinion, guidance/coaching COMPARE: simple DA pamphlet with clinical problem, options' outcomes	

Street 1995 (Continued)

Outcomes	uptake of option, knowledge, optimism	
Notes	Quality = 1 r=1 b=0 f=0	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

vanRoosmalen 2004

Methods	Video and pamphlet plus decision analysis vs video and pamphlet	
Participants	44 + 44 women diagnosed with BRCA 1/2 mutation considering prophylactic surgery	
Interventions	DA: video and brochure patient decision with decision analysis on options' outcomes, clinical problem, outcome probability, values clarification, guidance/coaching COMPARE: same video and brochure on options' outcomes, clinical problem, outcome probability, guidance/coaching	
Outcomes	decision uncertainty, perceived weighing pros/cons, perceived participation, anxiety, health outcomes	
Notes	Quality = 3 r=2 b=0 f=1	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Volk 1999

Methods	Video + pamphlet vs usual care	
Participants	80 + 80 men considering PSA testing	
Interventions	DA: videotape and brochure on options' outcomes, clinical problem, outcome probability, others' opinion COMPARE: usual care	
Outcomes	preferred option, knowledge, uptake of option, satisfaction with decision	
Notes	Quality = 3 r=2 b=0 f=1	

Volk 1999 (Continued)

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Vuorma 2003

Methods	Information booklet vs usual care	
Participants	184 + 179 women considering treatment for menorrhagia	
Interventions	DA: booklet on options' outcomes, clinical problem, outcome probability COMPARE: usual care	
Outcomes	uptake of option, knowledge, proportion remaining undecided, anxiety, satisfaction, health outcomes, use and cost of healthcare services	
Notes	Quality = 3 r=2 b=0 f=1	

<i>Risk of bias</i>		
Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Whelan 2003

Methods	Decision board and booklet vs standard care and booklet	
Participants	82 + 93 women with node negative breast cancer considering adjuvant chemotherapy	
Interventions	DA: Decision board and booklet on options' outcomes, clinical problem, outcome probability COMPARE: booklet on clinical problem	
Outcomes	preferred option, knowledge, anxiety, realistic expectations, satisfaction of patient, participation in decision making	
Notes	Quality = 3 r=2 b=0 f=1	

<i>Risk of bias</i>		
Item	Authors' judgement	Description

Whelan 2003 (Continued)

Allocation concealment?	Yes	A - Adequate
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Whelan 2004

Methods	Decision board vs standard care
Participants	94 + 107 women with Stage 1 or 2 breast cancer considering surgery
Interventions	DA: Decision board on options' outcomes, outcome probability COMPARE: usual care
Outcomes	preferred option, knowledge, realistic expectations, decisional conflict, anxiety, satisfaction
Notes	Quality = 3 r=2 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Wolf 1996

Methods	Script vs single sentence
Participants	103 + 102 men considering PSA testing
Interventions	DA: script of options' outcomes, clinical problem, outcome probability, others' opinions COMPARE: usual care
Outcomes	preferred option
Notes	Quality = 2 r=1 b=0 f=1

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Wolf 2000

Methods	Script vs 5 sentences
Participants	266 + 133 elderly (65+) considering colorectal cancer screening
Interventions	DA: script of options' outcomes, clinical problem, outcome probabilities COMPARE: usual care
Outcomes	preferred option, realistic expectations
Notes	Quality = 1 r=1 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Wong 2006

Methods	Decision aid leaflet vs placebo control leaflet
Participants	162 + 164 women referred for pregnancy termination
Interventions	DA: simple decision aid leaflet on options' outcomes, clinical problem, outcome probability, values clarification COMPARE: placebo leaflet on contraception use post pregnancy termination
Outcomes	uptake of option, knowledge, decisional conflict, anxiety
Notes	Quality = 2 r=2 b=0 f=0

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Characteristics of excluded studies *[ordered by study ID]*

Adab 2003	Hypothetical decision
Armstrong 2005	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid. Additional information requested from author but not provided.
Brown 2004	No specific decision to be made
Brundage 2001	Non-RCT design
Chadwick 1991	Non-RCT design, decision support minimal
Chewning 1999	Non-RCT design
Colella 2004	Describes model of care
Coulter 2003	Editorial
Crang-Svalenius 1996	Non-RCT design
Davison 1999	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid.
Flood 1996	Non-randomized allocation; waiting list control
Frosch 2001	Non-RCT design
Graham 2000	General information with no focused decision
Green 2001b	Educational intervention
Greenfield 1985	Intervention to increase patient involvement in care; no focused decision
Gruppen 1994	No decision aid
Healton 1999	No specific decision; No decision aid; education to promote compliance
Hewison 2001	Not a decision aid; no values clarification
Hickish 1995	Letter
Hochlehnert 2006	General information; no values clarification
Holloway 2003	Promotes complying with a recommended option
Hunt 2005	Promotes complying with a recommended option
Hunter 1999	Not focused on specific decision

(Continued)

Jorm 2003	Not at point of decision making - community sample asked to evaluate information booklet on depression
LaCroix 1999	Secondary report of pilot study
Lazcano Ponce 2000	No values clarification
Lewis 2003	Hypothetical decision
Maisels 1983	No values clarification
Manns 2005	Promotes complying with a recommended option
Markham 2003	Review of patient information pamphlets (pre-operative fasting)
Maslin 1998	Insufficient outcome data provided in publication. Requested from author but not provided.
Mazur 1994	Hypothetical decision
McGinley 2002	No values clarification
McInerney-Leo 2004	No risk/benefit information; no values clarification
Michie 1997	Unable to ascertain whether intervention meets criteria (values clarification) to qualify as a patient decision aid. Additional information requested but author was unable to provide the intervention.
Molenaar 2001	Non-RCT design
Mulley 2006	Editorial
Myers 2005b	Editorial
Newton 2001	Non-RCT design
O'Cathain 2002	Suite of 8 decision aids (not an efficacy trial)
O'Connor 1996	No patient decision aid - framing effects
Pearson2005	Focus on provision of information
Peele 2005	Decision aid only supplies mortality risk information; no risk info; no values clarification
Proctor 2006	General patient education resource
Rimer 2001	Promotes complying with a recommended option
Rimer 2002	Promotes complying with a recommended option

(Continued)

Rovner 2004	Non-RCT design
Ryser 2004	Promotes complying with a recommended option
Sheridan 2004	Non-RCT design
Sorenson 2004	Non-RCT design
Steiner 2003	Only effectiveness not cons of options; not at point of decision making
Street 1998	Promotes complying with a recommended option
Tabak 1995	No decision aid; non-RCT design
Thomson 2006	Non-RCT design; not at point of decision making
Thornton 1995	Unable to ascertain whether intervention meets criteria to qualify as a patient decision aid. Additional information requested from author but not provided.
Valdez 2001	Non-RCT; complying with a recommended option
Wagner 1995	Non-RCT
Wallston 1991	No decision aid - patient preference study
Wang 2004	Intent of intervention to facilitate genetic counselling process, no focused decision.
Willemsen 2006	Lifestyle change
Wroe 2005	Promotes complying with a recommended option
Zapka 2004	Promotes complying with a recommendation

Characteristics of ongoing studies *[ordered by study ID]*

Connelly

Trial name or title	Alternative approaches to support HRT decision making
Methods	
Participants	Peri & post menopausal women considering HRT
Interventions	discussion with practitioner versus audio-guided booklet + visit versus video + visit
Outcomes	satisfaction with menopausal care, knowledge, decisional conflict, likelihood to use HRT
Starting date	Trial complete
Contact information	Maureen Connelly , maureen.connelly@hphc.org
Notes	Paper being published

Cranny osteoporosis

Trial name or title	Osteoporosis treatment options decision aid
Methods	
Participants	Women considering treatment for osteoporosis
Interventions	Decision aid versus usual care controls
Outcomes	Knowledge, realistic expectations, preference for outcomes, decision, persistence with decision, physician perception of preference, decisional conflict, satisfaction with decision making process, preferred role in decision making, preparation for decision making, decision self-efficacy, decision regret, health promotion plans, SF-12, OPTQoL
Starting date	May 2001
Contact information	Ann Cranney University of Ottawa, Ottawa Health Research Institute C4 Ottawa Hospital 1053 Carling Ave Ottawa, K1Y 4E9 acranney@ohri.ca
Notes	

Hamm/Volk prostate

Trial name or title	Prostate cancer screening
Methods	
Participants	Men considering prostate cancer screening
Interventions	Decision aid balance sheet versus NCI pamphlets on prostate cancer screening
Outcomes	
Starting date	Ongoing
Contact information	Robert-Hamm@ouhsc.edu
Notes	

Krist/Woolf prostate

Trial name or title	Prostate cancer screening
Methods	
Participants	Men considering screening options for prostate cancer
Interventions	Decision aid via Internet versus ?
Outcomes	
Starting date	Ongoing
Contact information	ahkrist@vcu.edu
Notes	

Kupperman prenatal

Trial name or title	Prenatal diagnostic testing
Methods	
Participants	Couples considering prenatal diagnostic testing
Interventions	Decision aid computer program versus ?
Outcomes	
Starting date	Ongoing

Kupperman prenatal (Continued)

Contact information	kuppermannm@obgyn.ucsf.edu
Notes	

Leigh breast mets

Trial name or title	Breast Cancer Metastatic Decision Aid
Methods	
Participants	Women with metastatic breast cancer considering treatment options
Interventions	Decision aid versus usual care
Outcomes	Treatment decision; satisfaction with decision; knowledge; anxiety; decisional conflict; physician satisfaction with decision-making
Starting date	Sept. 2002
Contact information	Natasha Leighl, Princess Margaret Hospital, 5-222 610 University Avenue, Toronto, Ontario M5G 2M9, Canada; Telephone; 416-946-2399, Fax; 416-946-6546, email; natasha.leighl@uhn.on.ca
Notes	

Leighl colon mets

Trial name or title	Colon Cancer Metastatic Decision Aid
Methods	
Participants	Women and men with metastatic colon cancer considering treatment options
Interventions	Decision board, booklet and audiotape versus usual care.
Outcomes	Treatment decision; satisfaction with decision; knowledge; anxiety; decisional conflict; physician satisfaction with decision-making
Starting date	Dec. 2002
Contact information	Natasha Leighl, Princess Margaret Hospital, 5-222 610 University Avenue, Toronto, Ontario M5G 2M9, Canada; Telephone; 416-946-2399, Fax; 416-946-6546, email; natasha.leighl@uhn.on.ca
Notes	

Molewijk aneurysms

Trial name or title	Asymptomatic aorta aneurysm decision aid
Methods	
Participants	Adults considering treatment for asymptomatic aortic aneurysm
Interventions	Decision aid decision analysis with booklet versus ?
Outcomes	
Starting date	Ongoing
Contact information	Bert Molewijk A.C.Molewijk@lumc.nl
Notes	

Nagle 2006

Trial name or title	Evaluation of a decision aid for prenatal testing of fetal abnormalities: a cluster randomised trial
Methods	
Participants	Women considering prenatal diagnostic testing
Interventions	Decision aid versus pamphlet
Outcomes	Informed choice; decisional conflict; attitudes to fetus/neonate; depression; anxiety; satisfaction with decision
Starting date	Protocol published April 2006
Contact information	Cate Nagle - cate.nagle@mcri.edu.au
Notes	

Schapira HRT

Trial name or title	Menopause options
Methods	
Participants	Women considering menopause options
Interventions	Decision aid CD-Rom versus pamphlet
Outcomes	

Schapira HRT (Continued)

Starting date	Trial complete
Contact information	mschap@mcw.edu
Notes	

Scheid breastscreen

Trial name or title	Breast screening decision aid
Methods	
Participants	Women considering breast screening
Interventions	Decision aid computer balance sheets versus?
Outcomes	
Starting date	Ongoing
Contact information	Dewey Scheid (Dewey-Scheid@ouhsc.edu)
Notes	

Taylor prostate screening

Trial name or title	Prostate cancer screening decision aid
Methods	
Participants	African American men considering prostate cancer screening
Interventions	Decision aid videocassette versus ?
Outcomes	
Starting date	Ongoing
Contact information	Katheryn Taylor (TAYLORKL@gunet.georgetown.edu)
Notes	

Tiller ovarian prevention

Trial name or title	High risk ovarian cancer prevention
Methods	
Participants	Women at high risk for ovarian cancer
Interventions	Decision aid booklet versus general education pamphlet
Outcomes	
Starting date	June 2001 to December 2003
Contact information	k.tiller@unsw.edu.au
Notes	

VanSteenkiste cholesterol

Trial name or title	Decision aid to enhance implementation of cholesterol guideline in general practice
Methods	
Participants	45 general practitioners (19 intervention, 26 controls) to recruit 20 patients each
Interventions	Decision aid booklet, embedded in an extensive educational group session versus normal care (no booklet)
Outcomes	Adherence to cholesterol guideline (GP), self-efficacy (GP), satisfaction with consultation (P), satisfaction with the decision aid (P), self-reported lifestyle, risk perception (p), Weariness (P)
Starting date	Trial complete
Contact information	Ben VanSteenkiste Centre of Quality of Care Research Department of General Practice Maastricht University PO Box 616 6200 MD Maastricht The Netherlands Ben.vansteenkiste@hag.unimaas.nl
Notes	

Whelan mixed formats

Trial name or title	Development and evaluation of different versions of the decision board for early breast cancer
Methods	

Whelan mixed formats (Continued)

Participants	Medical oncologists at the Hamilton Regional Cancer Centre and surgeons in Hamilton and surrounding area
Interventions	Standard version of the decision board versus computerized version of the decision board versus paper version of the decision board
Outcomes	Patient comprehension, usefulness of the decision board, patient satisfaction with the decision board, physician satisfaction and usefulness of the decision board
Starting date	April 2002
Contact information	Tim Whelan (Hamilton Regional Cancer Centre, tim.whelan@hrcc.on.ca) or Shelley Chambers (shelley.chambers@hrcc.on.ca)
Notes	

DATA AND ANALYSES

Comparison 1. Decision aids (DA) versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge: DA vs usual care	18	3491	Mean Difference (IV, Random, 95% CI)	15.18 [11.66, 18.69]
2 Decisional conflict: DA vs usual care	14		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Uncertainty subscale	12	2333	Mean Difference (IV, Random, 95% CI)	-0.94 [-3.29, 1.40]
2.2 Uninformed subscale	10	1839	Mean Difference (IV, Random, 95% CI)	-8.31 [-11.85, -4.78]
2.3 Unclear values subscale	8	1433	Mean Difference (IV, Random, 95% CI)	-6.35 [-10.02, -2.67]
2.4 Unsupported subscale	8	1433	Mean Difference (IV, Random, 95% CI)	-5.97 [-10.40, -1.55]
2.5 Ineffective choice subscale	11	2065	Mean Difference (IV, Random, 95% CI)	-5.69 [-8.93, -2.46]
2.6 Total decisional conflict score	10	1850	Mean Difference (IV, Random, 95% CI)	-6.12 [-8.62, -3.63]
3 Participation in decision making: DA vs usual care	8		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
3.1 Patient controlled decision making	7	1106	Risk Ratio (M-H, Random, 95% CI)	1.65 [1.02, 2.65]
3.2 Shared decision making	7	1106	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.78, 1.25]
3.3 Practitioner controlled decision making	8	1277	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.45, 0.82]
4 Satisfaction with the decision making process: DA vs usual care	3		Mean Difference (IV, Random, 95% CI)	Totals not selected
5 Satisfaction with the decision: DA vs usual care	3		Mean Difference (IV, Random, 95% CI)	Totals not selected
6 Behaviour: Reduced proportion remaining undecided, DA vs usual care	4	1032	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.34, 0.75]
7 Choice: Surgery over conservative option: DA vs usual care	8		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
7.1 As treated analysis	8	1875	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.59, 0.94]
7.2 Intention to treat analysis	8	2069	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.60, 0.94]
8 Choice: PSA screening: DA vs usual care	5	1442	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.66, 0.98]
9 Choice: Colon screening FOBT + sigmoid: DA vs usual care	3	735	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.70, 1.85]
10 Choice: Breast cancer genetic testing: DA vs usual care	4	949	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.83, 1.22]

Comparison 2. Detailed versus simple decision aids

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Knowledge: Detailed vs simple decision aids	9	1261	Mean Difference (IV, Random, 95% CI)	4.63 [3.02, 6.24]
2 Decisional conflict: Detailed vs simple decision aid	9		Mean Difference (IV, Random, 95% CI)	Subtotals only
2.1 Uncertainty subscale	7	865	Mean Difference (IV, Random, 95% CI)	-2.43 [-8.58, 3.72]
2.2 Uninformed subscale	5	612	Mean Difference (IV, Random, 95% CI)	-1.32 [-5.27, 2.62]
2.3 Unclear values subscale	5	609	Mean Difference (IV, Random, 95% CI)	-1.05 [-4.81, 2.70]
2.4 Unsupported subscale	5	614	Mean Difference (IV, Random, 95% CI)	-0.80 [-3.77, 2.17]
2.5 Ineffective choice subscale	5	613	Mean Difference (IV, Random, 95% CI)	-0.04 [-3.93, 3.86]
2.6 Total decisional conflict score	7	1023	Mean Difference (IV, Random, 95% CI)	-1.34 [-3.33, 0.64]
3 Participation in decision making: Detailed vs simple decision aid	1		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
3.1 Patient controlled decision making	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
3.2 Shared decision making	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
3.3 Practitioner controlled decision making	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
4 Behaviour: Reduced proportion remaining undecided: Detailed vs simple decision aids	2	292	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.66, 1.62]
5 Choice: Surgery over conservative option: Detailed vs simple decision aid	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 As treated analysis	2	404	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.55, 1.01]
5.2 Intention to treat analysis	2	453	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.57, 1.07]
6 Choice: PSA screening: Detailed vs simple decision aid	3	677	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.81, 1.17]
7 Choice: Hormone replacement therapy: Detailed vs simple decision aid	3	357	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.55, 0.98]
8 Choice: Prenatal diagnostic testing: Detailed vs simple decision aid	2	443	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.85, 1.04]

Comparison 3. Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information

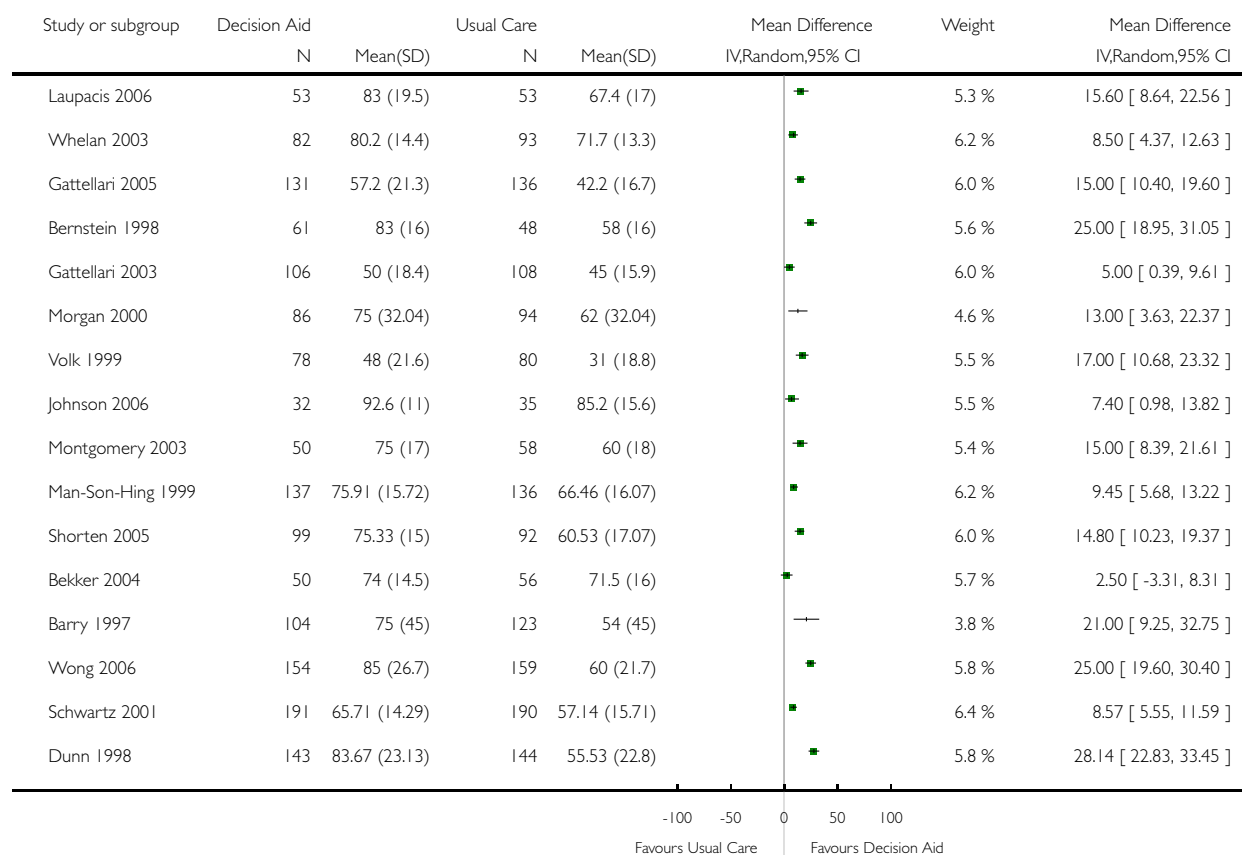
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Accurate risk perceptions	11	2953	Risk Ratio (M-H, Random, 95% CI)	1.61 [1.35, 1.92]
2 Accurate risk perceptions - numbers	8	2011	Risk Ratio (M-H, Random, 95% CI)	1.81 [1.43, 2.29]
3 Accurate risk perceptions - words	3	942	Risk Ratio (M-H, Random, 95% CI)	1.27 [1.09, 1.48]

Analysis 1.1. Comparison 1 Decision aids (DA) versus usual care, Outcome 1 Knowledge: DA vs usual care.

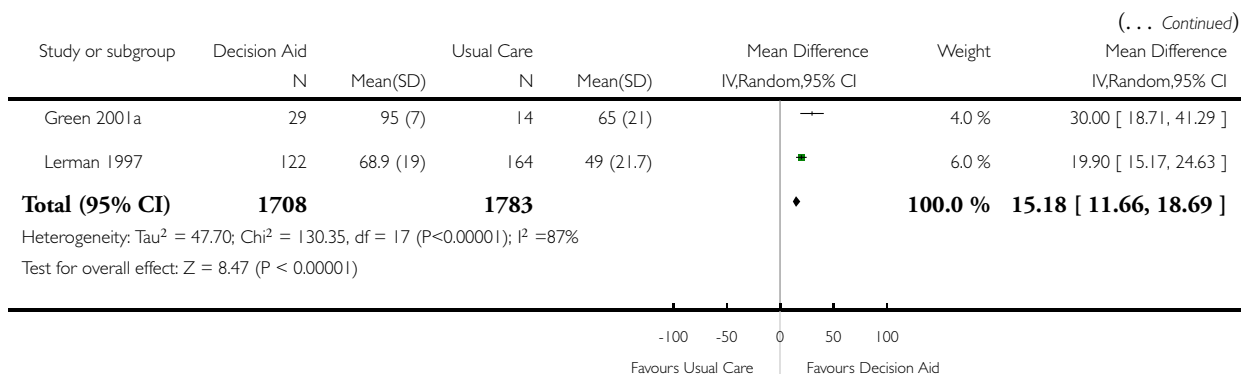
Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 1 Knowledge: DA vs usual care



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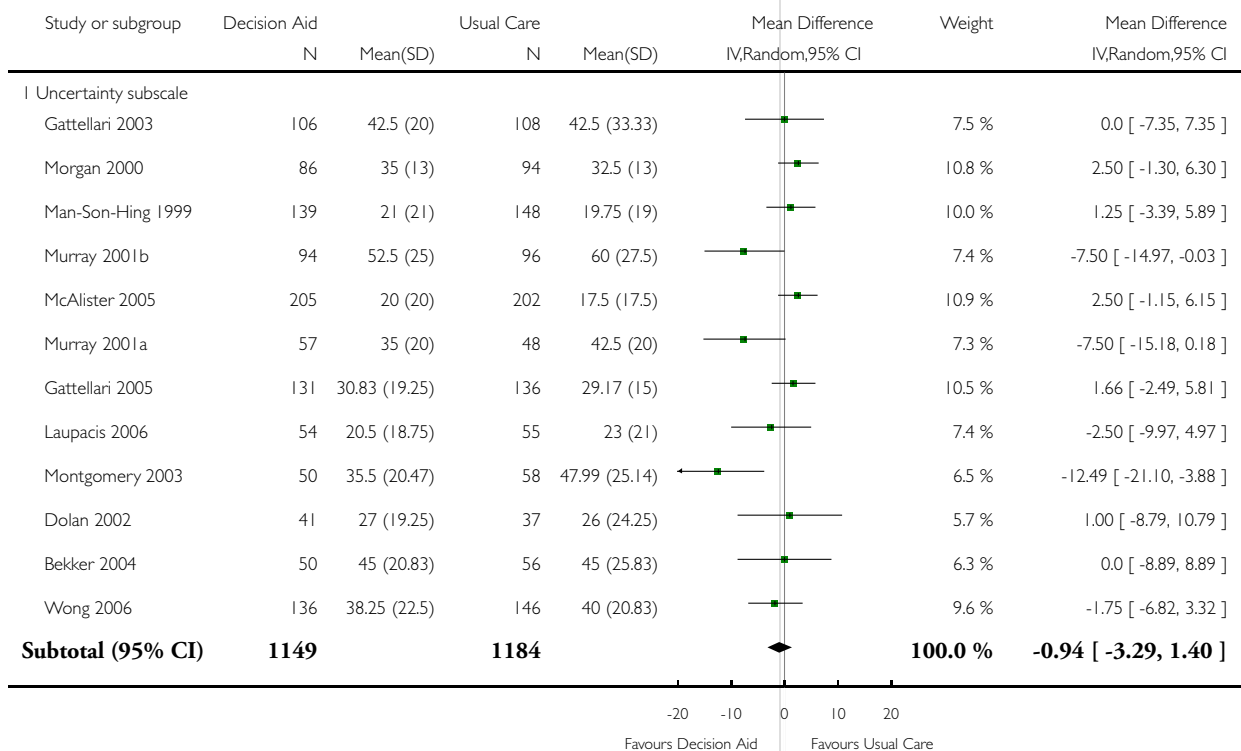


Analysis 1.2. Comparison 1 Decision aids (DA) versus usual care, Outcome 2 Decisional conflict: DA vs usual care.

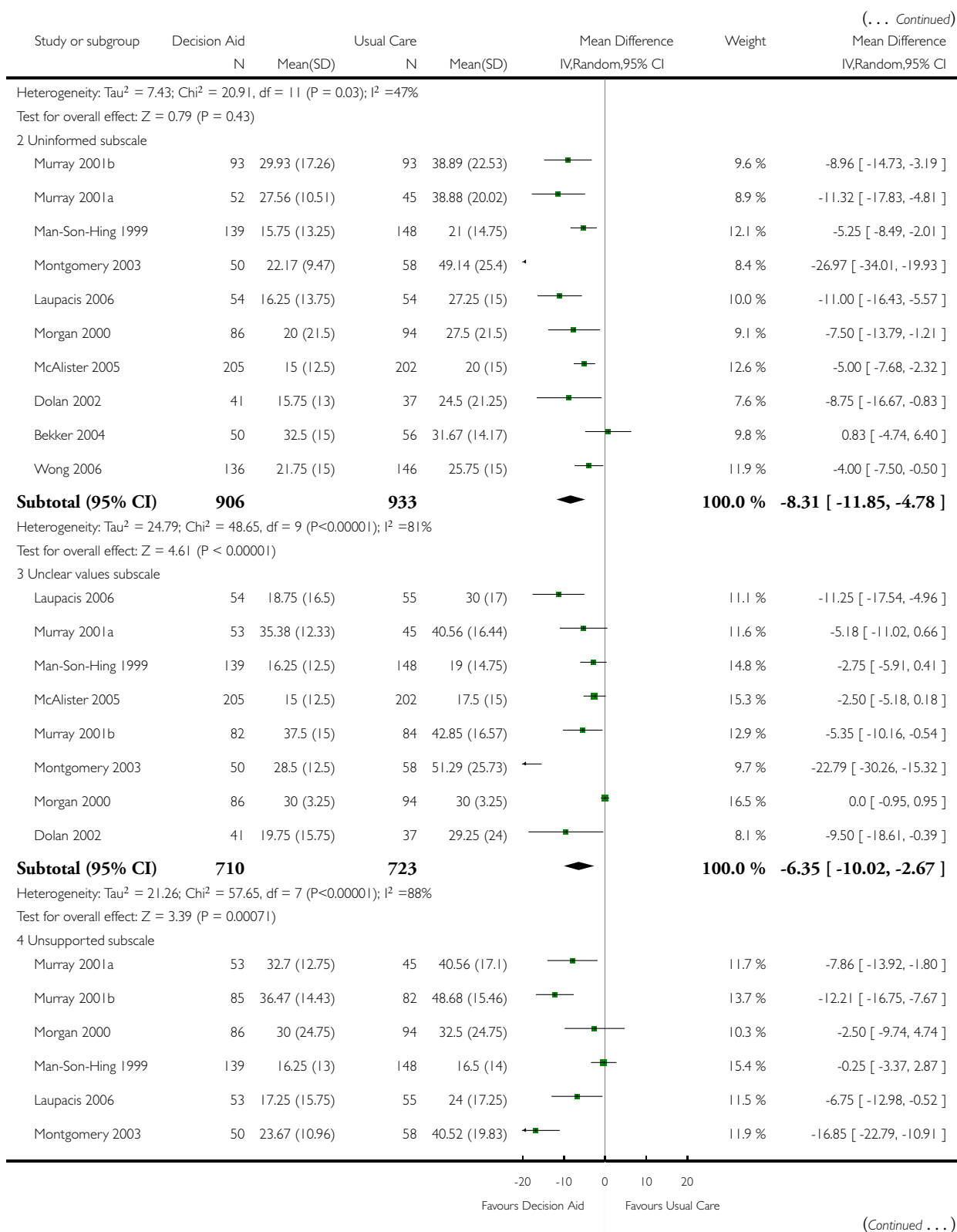
Review: Decision aids for people facing health treatment or screening decisions

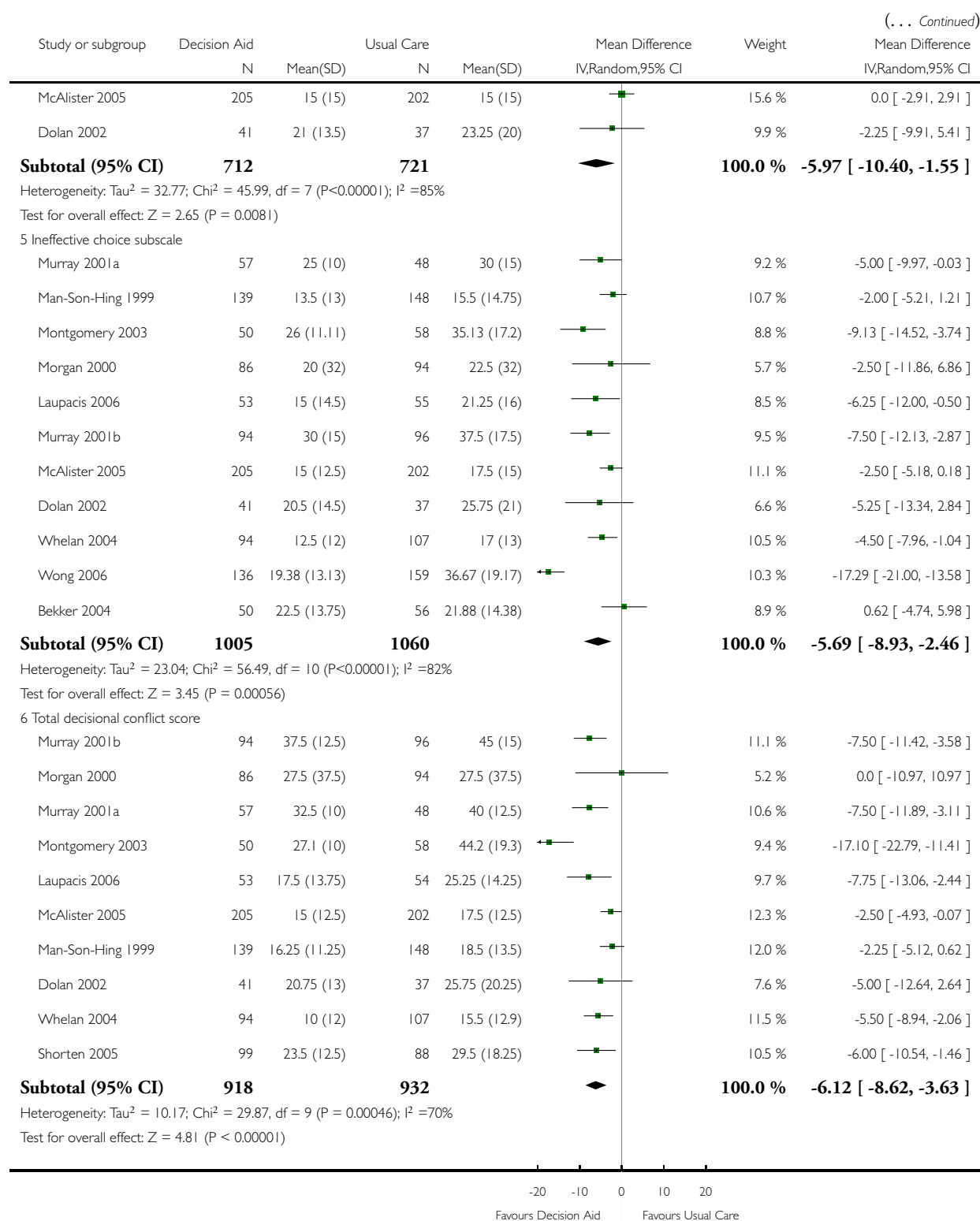
Comparison: 1 Decision aids (DA) versus usual care

Outcome: 2 Decisional conflict: DA vs usual care



(Continued . . .)



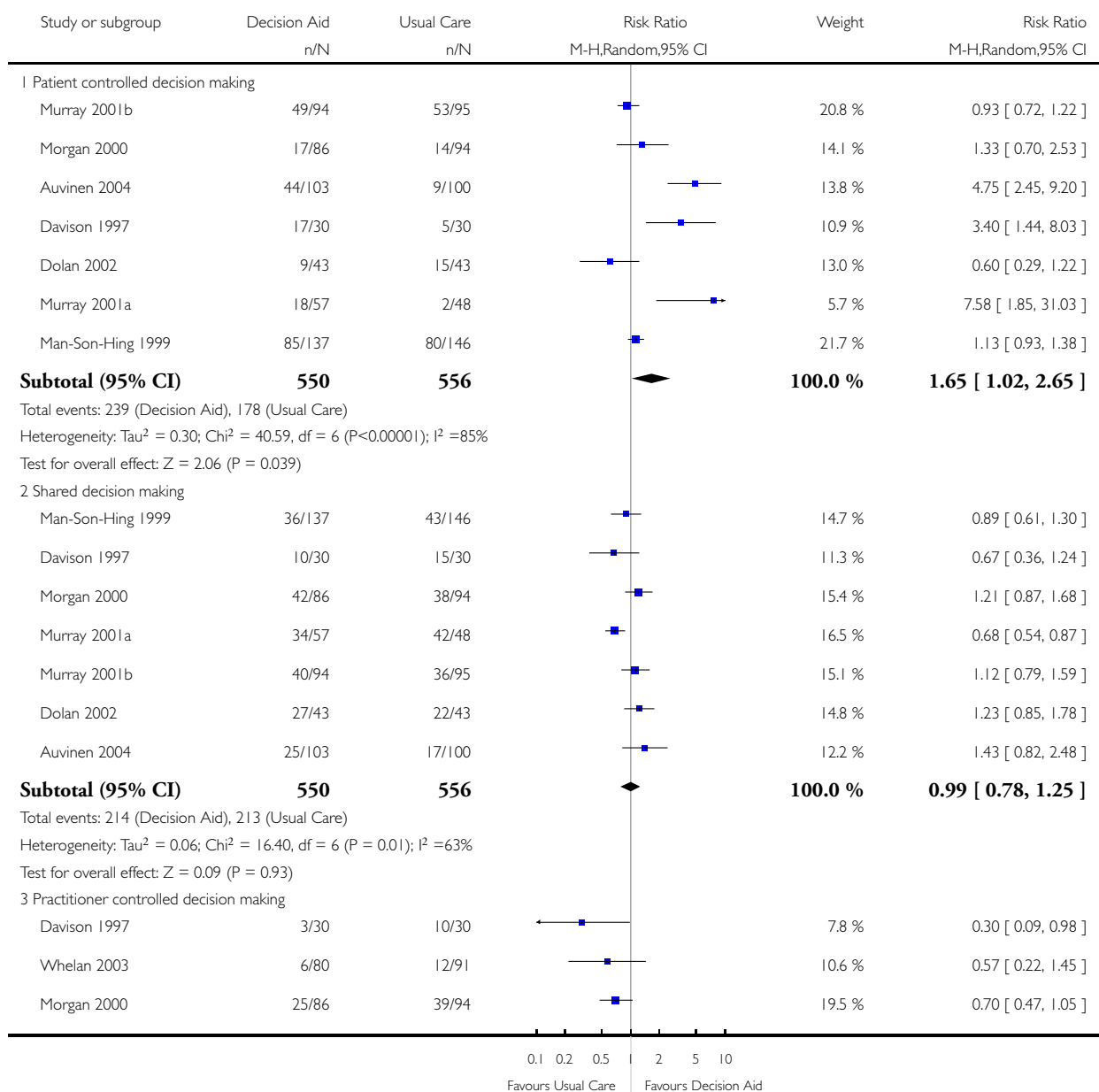


Analysis 1.3. Comparison 1 Decision aids (DA) versus usual care, Outcome 3 Participation in decision making: DA vs usual care.

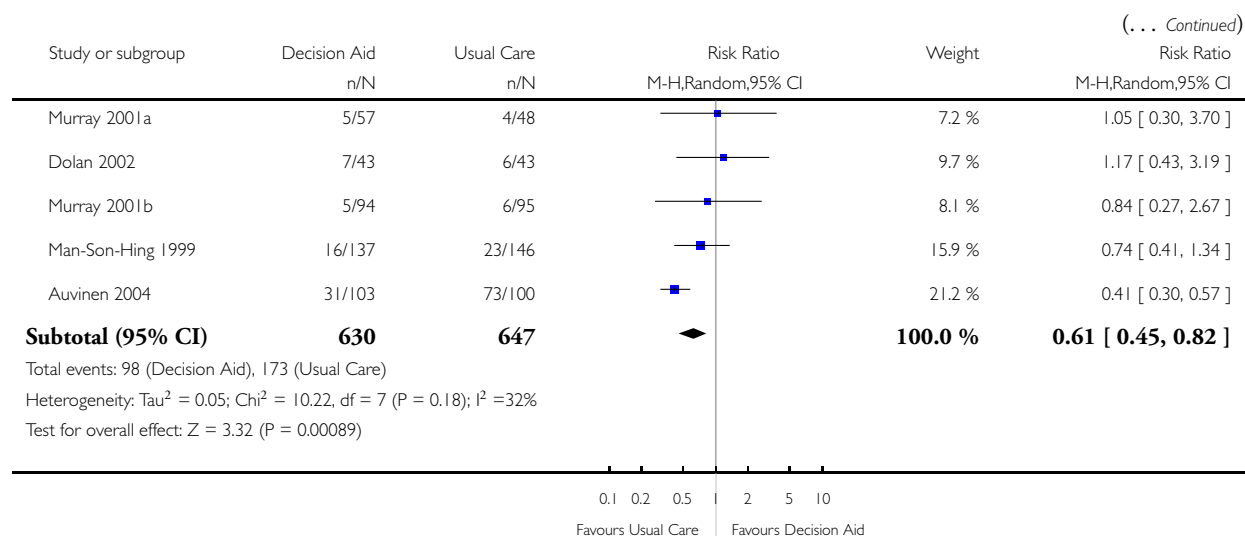
Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 3 Participation in decision making: DA vs usual care



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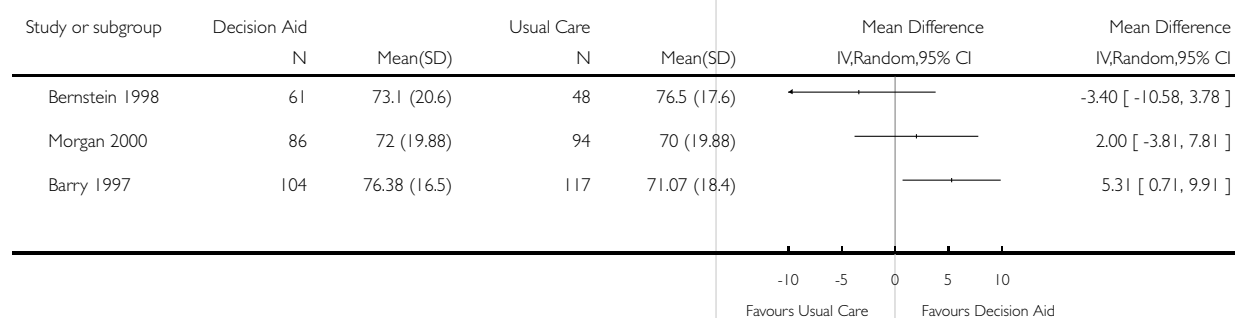


Analysis 1.4. Comparison 1 Decision aids (DA) versus usual care, Outcome 4 Satisfaction with the decision making process: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 4 Satisfaction with the decision making process: DA vs usual care

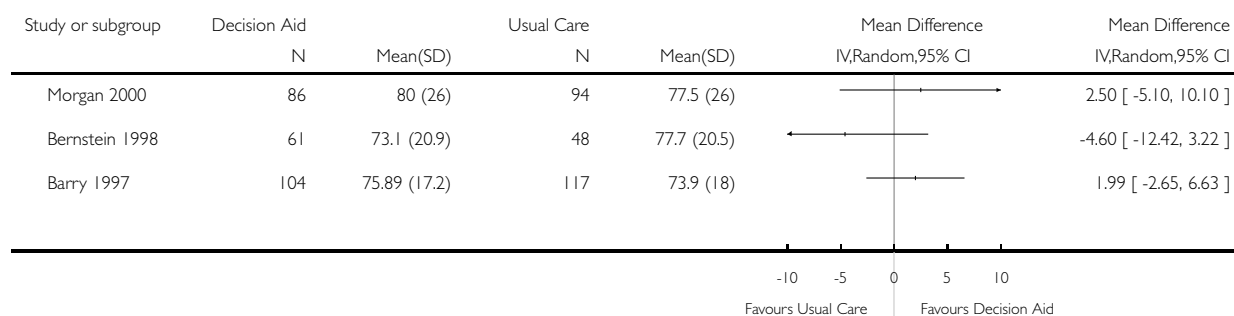


Analysis 1.5. Comparison 1 Decision aids (DA) versus usual care, Outcome 5 Satisfaction with the decision: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 5 Satisfaction with the decision: DA vs usual care

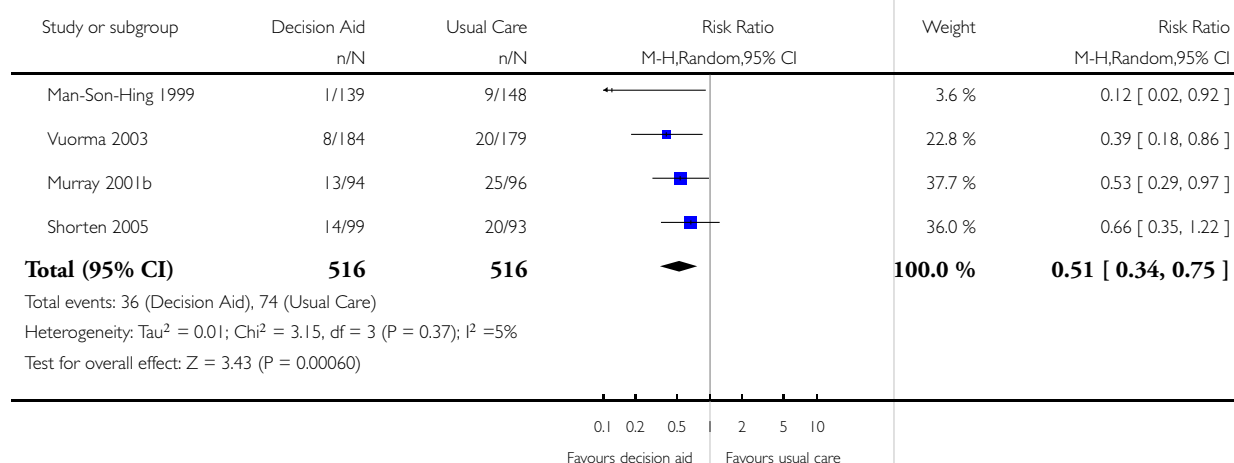


Analysis 1.6. Comparison 1 Decision aids (DA) versus usual care, Outcome 6 Behaviour: Reduced proportion remaining undecided, DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 6 Behaviour: Reduced proportion remaining undecided, DA vs usual care

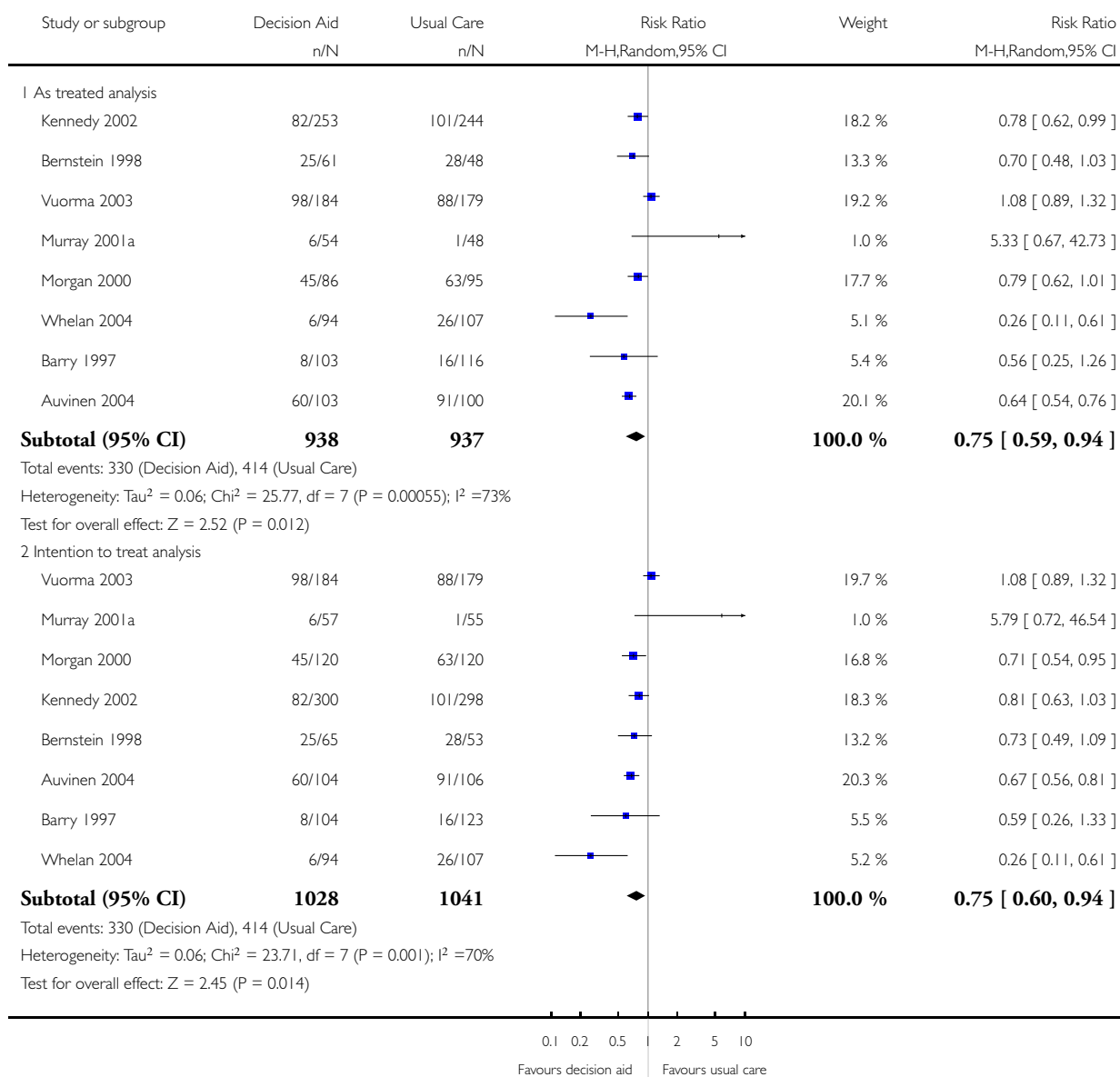


Analysis 1.7. Comparison 1 Decision aids (DA) versus usual care, Outcome 7 Choice: Surgery over conservative option: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 7 Choice: Surgery over conservative option: DA vs usual care

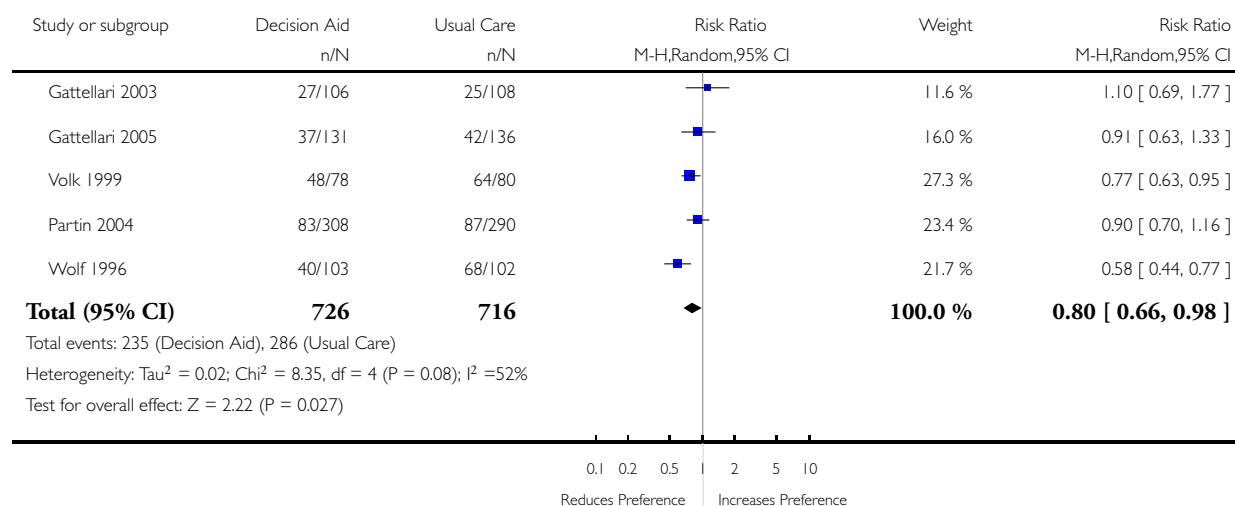


Analysis 1.8. Comparison 1 Decision aids (DA) versus usual care, Outcome 8 Choice: PSA screening: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 8 Choice: PSA screening: DA vs usual care

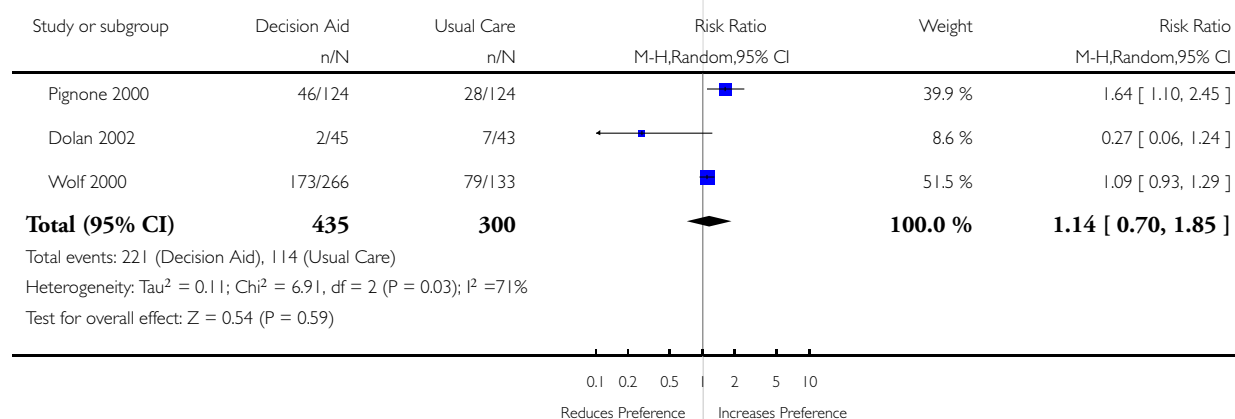


Analysis 1.9. Comparison 1 Decision aids (DA) versus usual care, Outcome 9 Choice: Colon screening FOBT + sigmoid: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 9 Choice: Colon screening FOBT + sigmoid: DA vs usual care

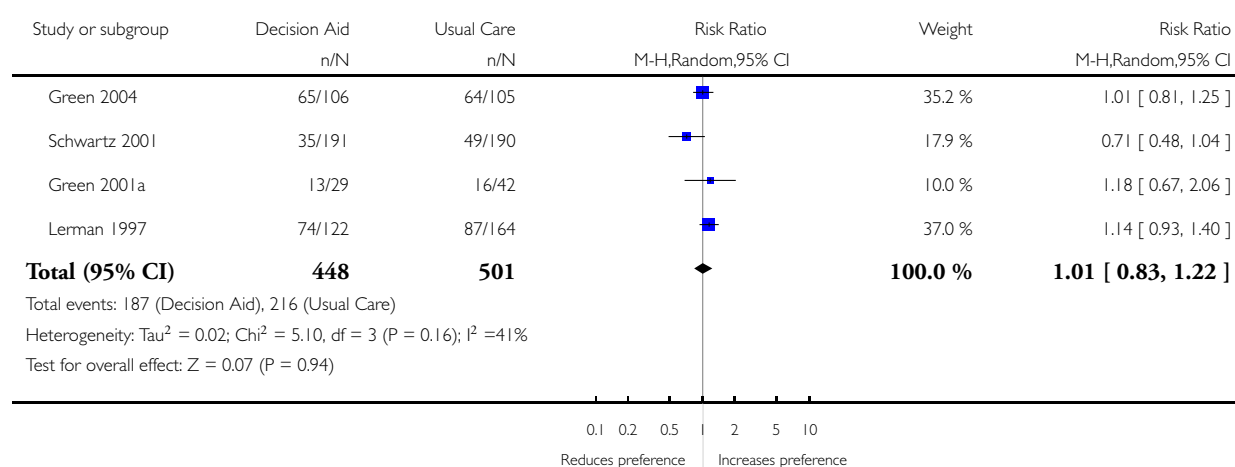


Analysis 1.10. Comparison 1 Decision aids (DA) versus usual care, Outcome 10 Choice: Breast cancer genetic testing: DA vs usual care.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 1 Decision aids (DA) versus usual care

Outcome: 10 Choice: Breast cancer genetic testing: DA vs usual care

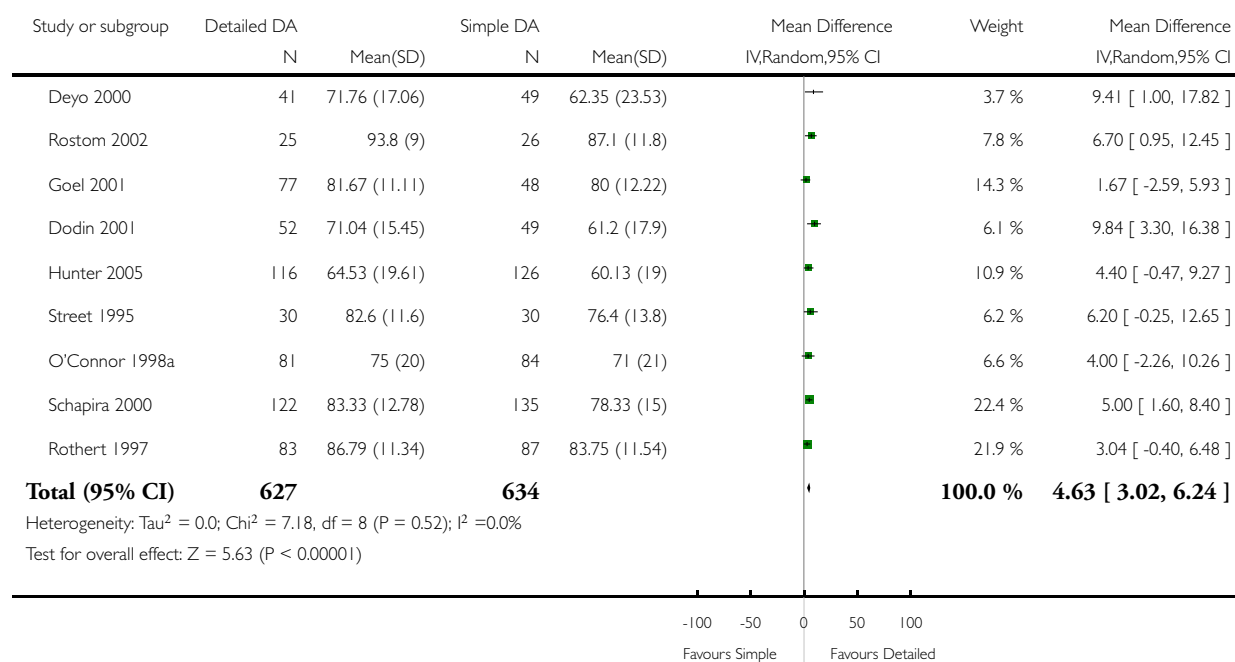


Analysis 2.1. Comparison 2 Detailed versus simple decision aids, Outcome 1 Knowledge: Detailed vs simple decision aids.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 1 Knowledge: Detailed vs simple decision aids

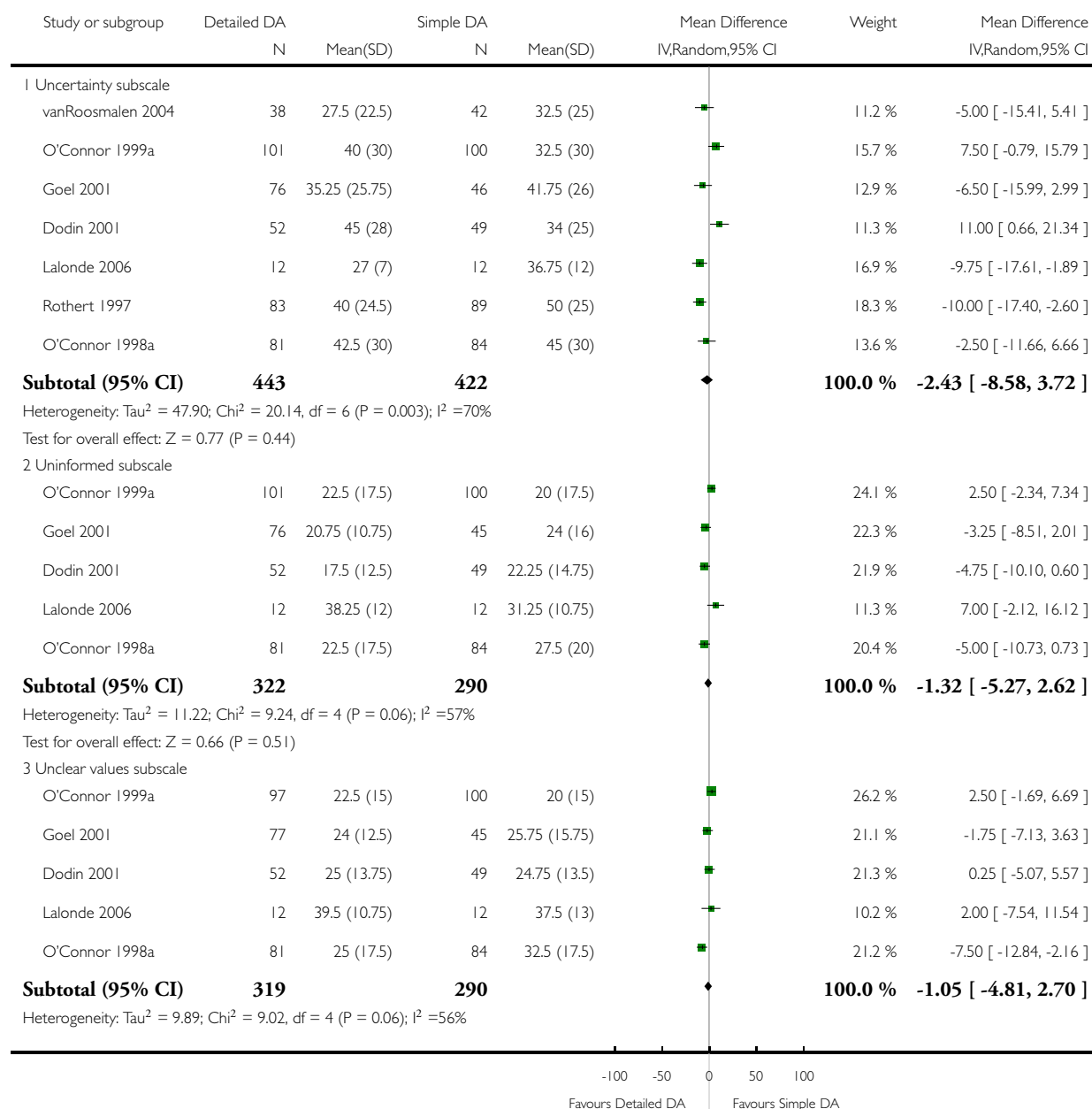


Analysis 2.2. Comparison 2 Detailed versus simple decision aids, Outcome 2 Decisional conflict: Detailed vs simple decision aid.

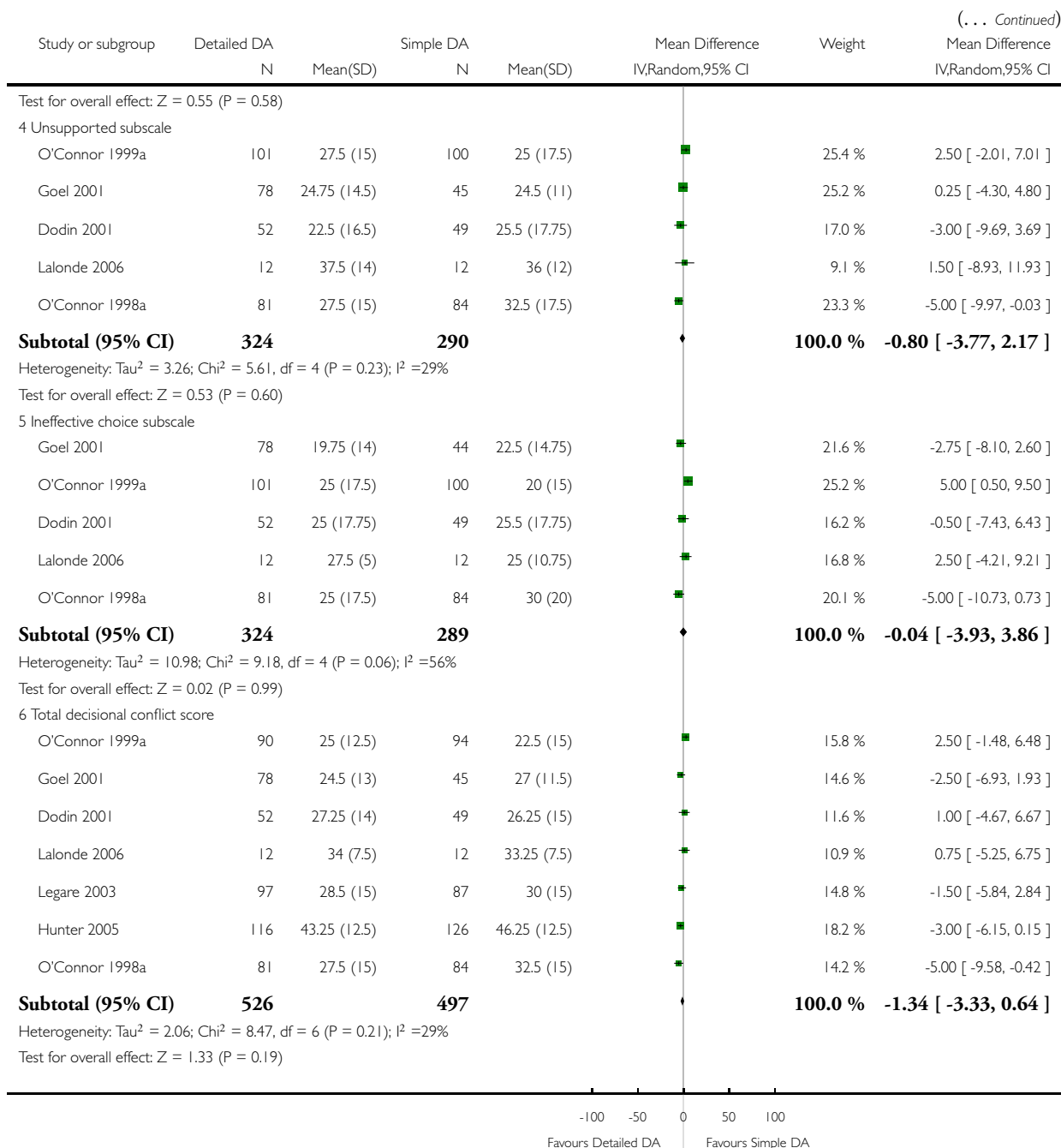
Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 2 Decisional conflict: Detailed vs simple decision aid



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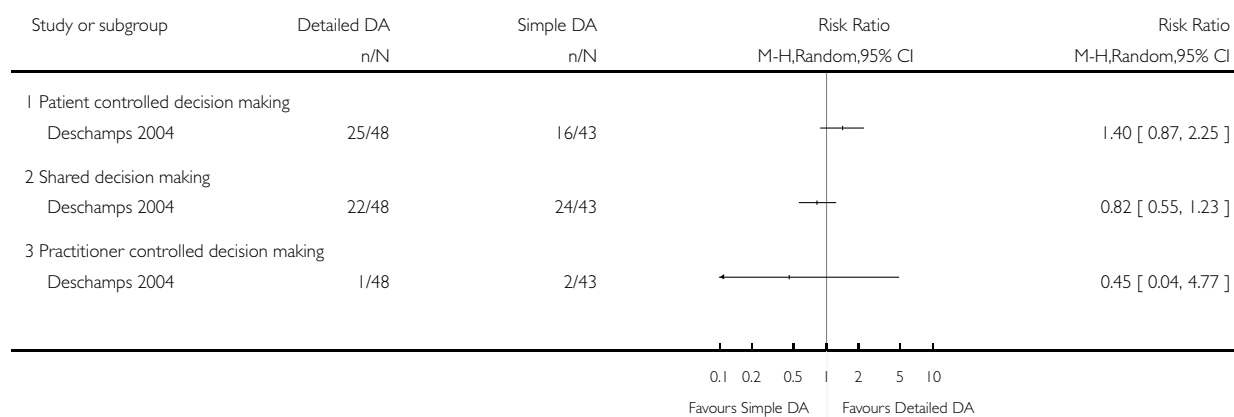


Analysis 2.3. Comparison 2 Detailed versus simple decision aids, Outcome 3 Participation in decision making: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 3 Participation in decision making: Detailed vs simple decision aid

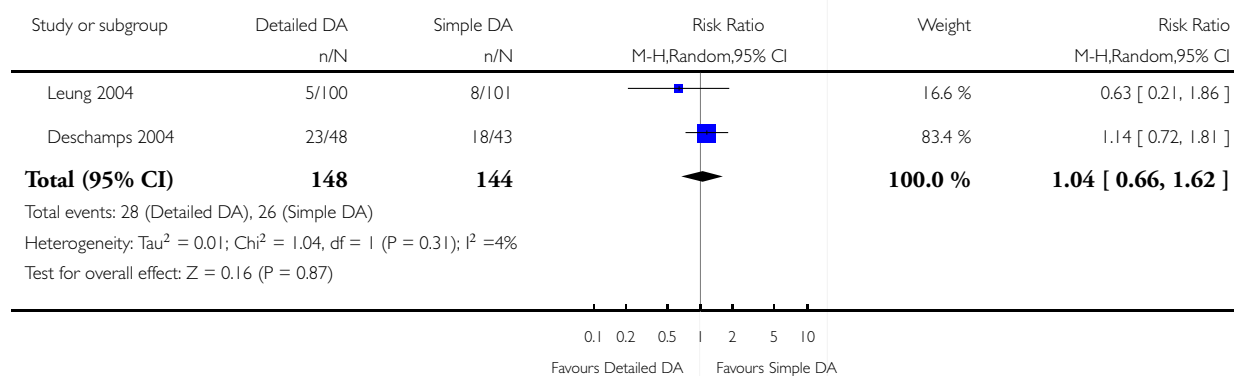


Analysis 2.4. Comparison 2 Detailed versus simple decision aids, Outcome 4 Behaviour: Reduced proportion remaining undecided: Detailed vs simple decision aids.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 4 Behaviour: Reduced proportion remaining undecided: Detailed vs simple decision aids

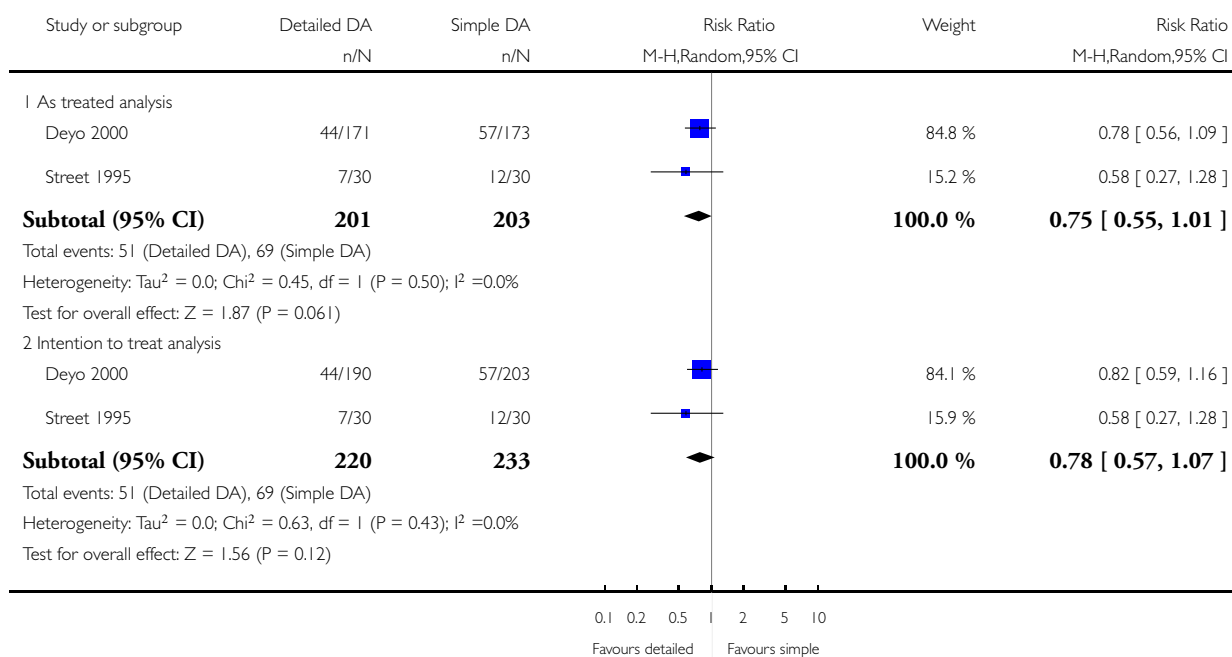


Analysis 2.5. Comparison 2 Detailed versus simple decision aids, Outcome 5 Choice: Surgery over conservative option: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 5 Choice: Surgery over conservative option: Detailed vs simple decision aid

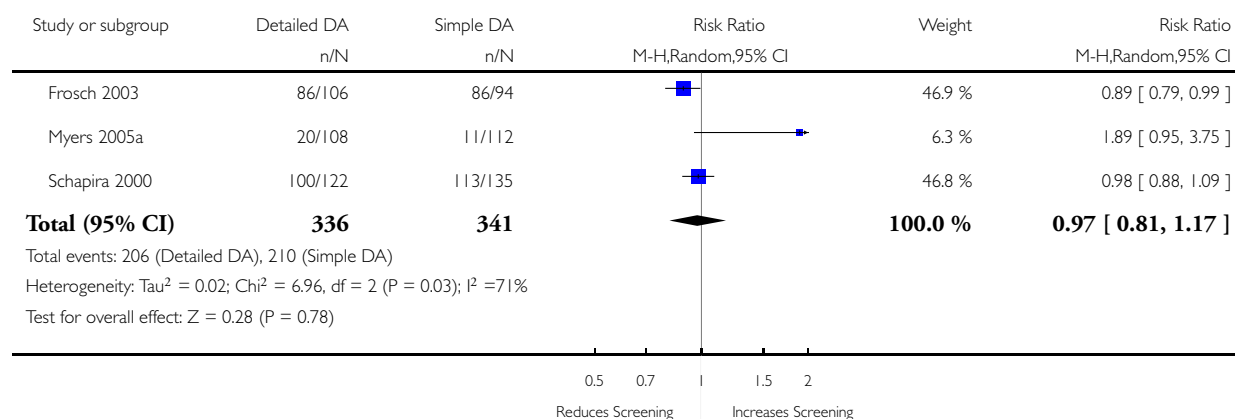


Analysis 2.6. Comparison 2 Detailed versus simple decision aids, Outcome 6 Choice: PSA screening: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 6 Choice: PSA screening: Detailed vs simple decision aid

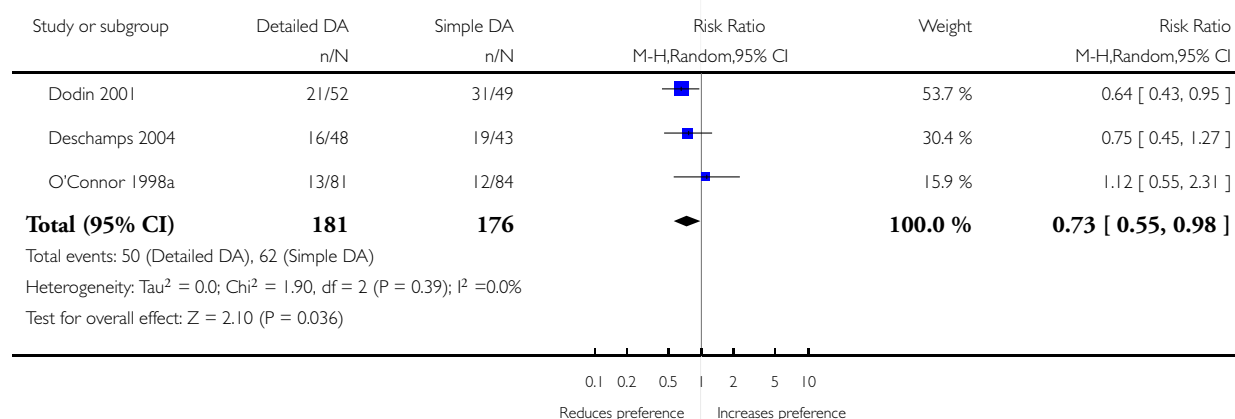


Analysis 2.7. Comparison 2 Detailed versus simple decision aids, Outcome 7 Choice: Hormone replacement therapy: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 7 Choice: Hormone replacement therapy: Detailed vs simple decision aid

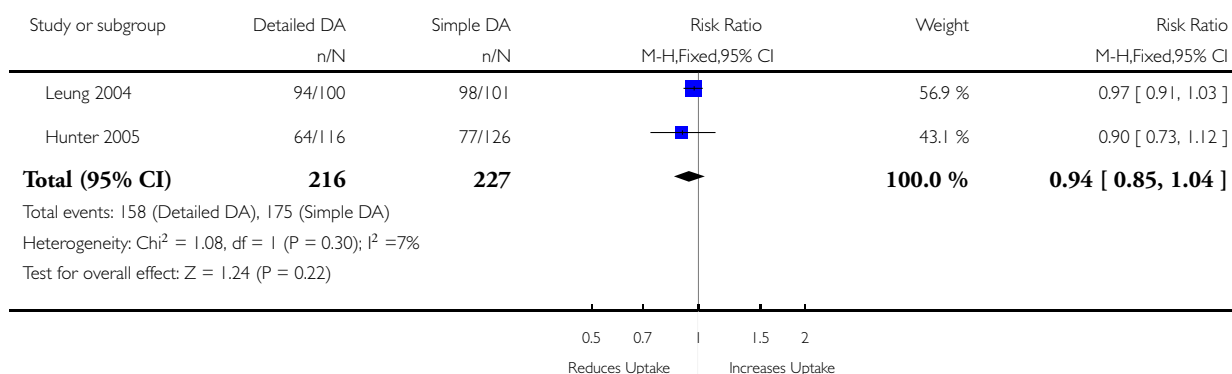


Analysis 2.8. Comparison 2 Detailed versus simple decision aids, Outcome 8 Choice: Prenatal diagnostic testing: Detailed vs simple decision aid.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 2 Detailed versus simple decision aids

Outcome: 8 Choice: Prenatal diagnostic testing: Detailed vs simple decision aid

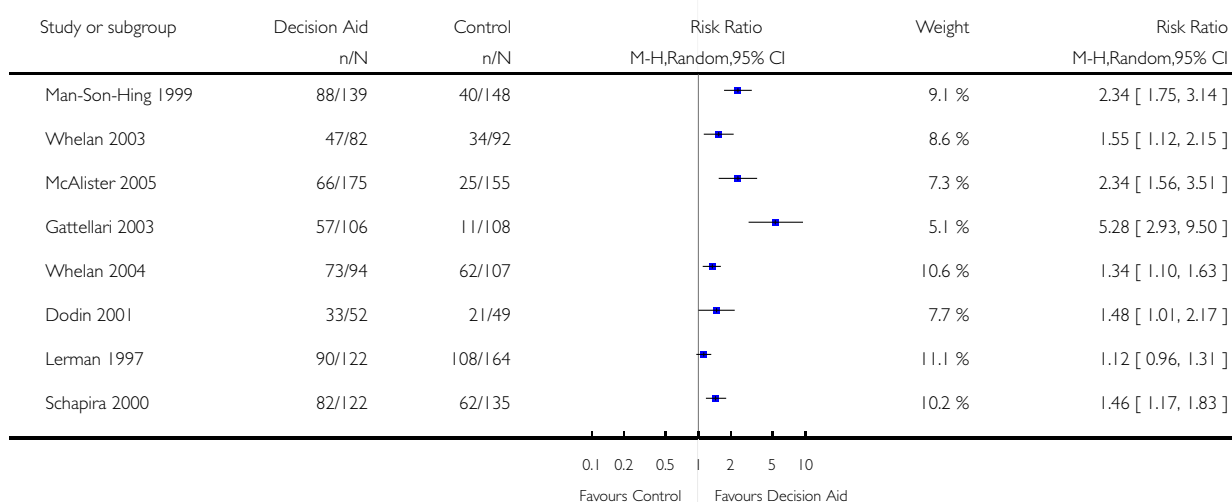


Analysis 3.1. Comparison 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information, Outcome 1 Accurate risk perceptions.

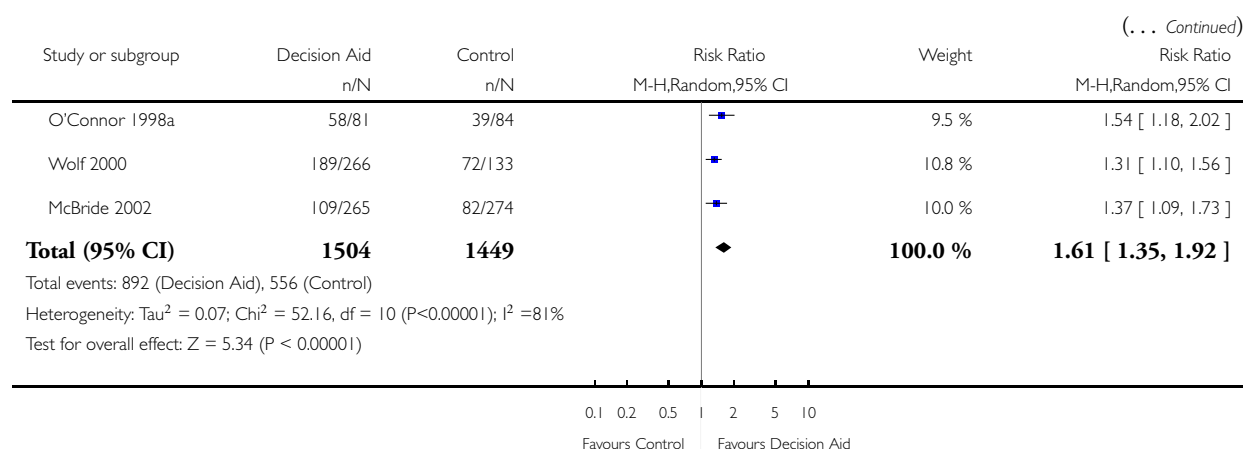
Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information

Outcome: 1 Accurate risk perceptions



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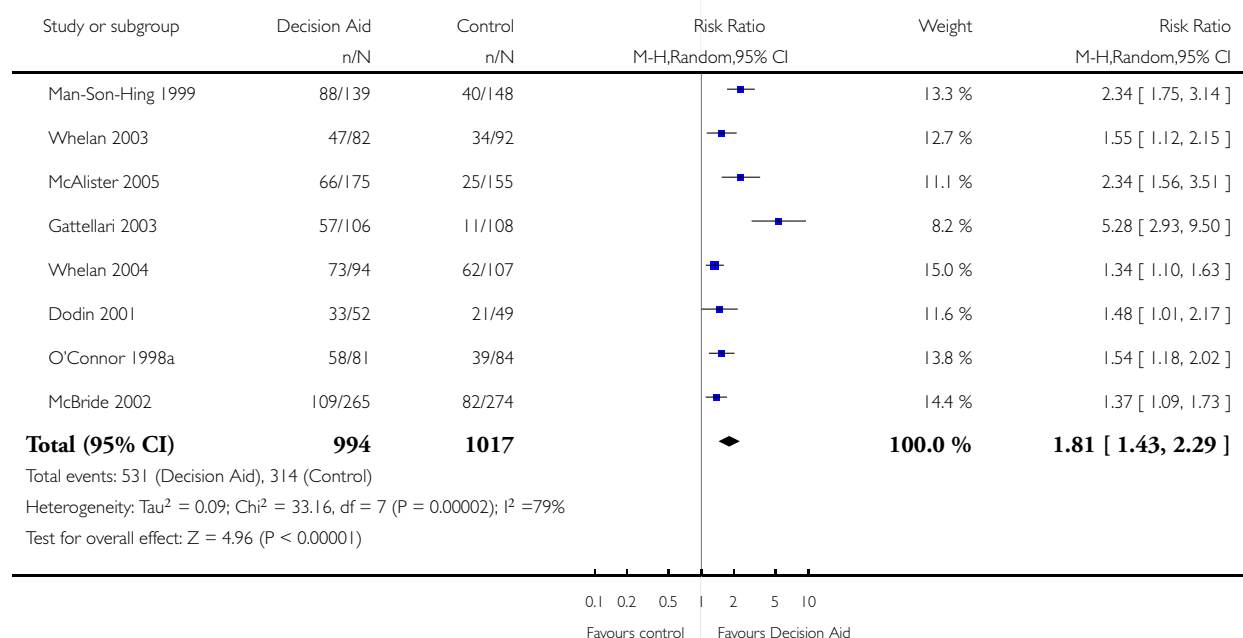


Analysis 3.2. Comparison 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information, Outcome 2 Accurate risk perceptions - numbers.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information

Outcome: 2 Accurate risk perceptions - numbers

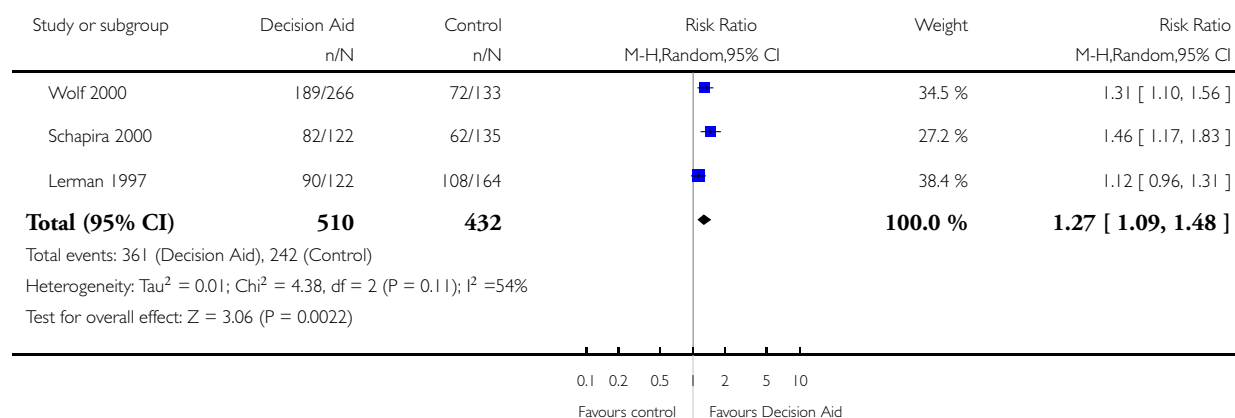


Analysis 3.3. Comparison 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information, Outcome 3 Accurate risk perceptions - words.

Review: Decision aids for people facing health treatment or screening decisions

Comparison: 3 Accurate risk perceptions: Decision aid with outcome probabilities vs no outcome probability information

Outcome: 3 Accurate risk perceptions - words



APPENDICES

Appendix I. MEDLINE search strategy

MEDLINE,1966 to July 2006, OVID platform

001 choice behavior/

002 decision making/

003 exp decision support techniques/

004 Educational Technology/

005 decision\$.tw.

006 (choic\$ or preference\$).tw.

007 communication package.tw.

008 or/1-7

009 exp health education/

010 Health knowledge, Attitudes, Practice/

011 informed consent.tw,hw.

012 patient.tw,hw.

013 consumer.tw,hw.

014 or/9-13

015 8 and 14

016 ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.

017 ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.

018 (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.

019 ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.

020 shared decision making.tw.

021 decision aid\$.tw.

022 informed choice.tw.

023 or/16-22
 024 15 or 23
 025 clinical trial.pt.
 026 randomised controlled trial.pt.
 027 random\$.tw.
 028 (double adj blind\$.tw.
 029 double-blind method/
 030 or/25-29
 031 24 and 30

Appendix 2. CENTRAL search strategy

CENTRAL, *The Cochrane Library*, Issue 2 2006

001 choice behavior/
 002 decision making/
 003 exp decision support techniques/
 004 Educational Technology/
 005 decision\$.tw.
 006 (choic\$ or preference\$).tw.
 007 communication package.tw.
 008 or/1-7
 009 exp health education/
 010 Health knowledge, Attitudes, Practice/
 011 informed consent.tw,hw.
 012 patient.tw,hw.
 013 consumer.tw,hw.
 014 or/9-13
 015 8 and 14
 016 ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
 017 ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
 018 (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
 019 ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
 020 shared decision making.tw.
 021 decision aid\$.tw.
 022 informed choice.tw.
 023 or/16-22
 024 15 or 23

Appendix 3. CINAHL search strategy

CINAHL, 1982 to July 2006, OVID platform

001 exp Decision Making/
 002 information seeking behavior/
 003 Help Seeking Behavior/
 004 (choic\$ or preference\$).tw.
 005 decision\$.tw.
 006 Educational Technology/
 007 or/1-6
 008 exp Health Behavior/
 009 consumer participation/
 010 exp Health Education/
 011 health knowledge/ or exp professional knowledge/
 012 exp Consent/

013 informed consent.tw.
 014 patient.tw,hw.
 015 consumer.tw,sh.
 016 or/8-15
 017 7 and 16
 018 ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
 019 ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
 020 (parent\$ adj1 (decision\$ or choice or preferenc\$ or participati\$)).tw.
 021 ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
 022 shared decision making.tw.
 023 decision aid\$.tw.
 024 informed choice.tw.
 025 or/18-24
 026 17 or 25
 027 exp clinical trials/
 028 Clinical trial.pt.
 029 (clinic\$ adj trial\$1).tw.
 030 random\$.tw.
 031 Random assignment/
 032 placebo\$.tw,sh.
 033 Quantitative studies/
 034 Allocat\$ random\$.tw.
 035 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj (blind\$3 or mask\$3)).tw.
 036 or/27-35
 037 26 and 36

Appendix 4. EMBASE search strategy

EMBASE, 1980 to July 2006, OVID platform

001 decision making/
 002 decision theory/
 003 decision\$.tw.
 004 Educational Technology/
 005 or/1-4
 006 exp health behavior/
 007 exp Patient Attitude/
 008 exp health education/
 009 informed consent.tw,sh.
 010 patient.tw,sh.
 011 consumer.tw,sh.
 012 or/6-11
 013 5 and 12
 014 ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw.
 015 ((women or men) adj1 (decision\$ or choice or preference or participation)).tw.
 016 (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw.
 017 ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw.
 018 shared decision making.tw.
 019 decision aid\$.tw.
 020 informed choice.tw.
 021 or/14-20
 022 13 or 21
 023 Controlled Study/
 024 Randomized Controlled Trial/

025 Clinical Study/
 026 Clinical Trial/
 027 Major Clinical Study/
 028 Prospective Study/
 029 Multicenter Study/
 030 Randomization/
 031 Double Blind Procedure/
 032 Single Blind Procedure/
 033 Crossover Procedure/
 034 Placebo.tw,sh.
 035 random\$.tw.
 036 (double adj blind\$).tw.
 037 or/23-36
 038 22 and 37

Appendix 5. PsycINFO search strategy

PsycINFO, 1806 to July 2006, OVID platform

001 decision\$.tw.
 002 (choice\$ or preference\$).tw.
 003 exp decision making/
 004 computer assisted instruction/
 005 or/1-4
 006 exp health education/
 007 exp health personnel attitudes/
 008 informed consent.tw,sh.
 009 patient.tw,hw.
 010 consumer.tw,hw.
 011 exp health behavior/
 012 or/6-11
 013 5 and 12
 014 ((patient\$ or consumer\$) adj1 (decision\$ or choice or preference or participation)).tw
 015 ((women or men) adj1 (decision\$ or choice or preference or participation)).tw
 016 (parent\$ adj1 (decision\$ or choice or preferenc\$ or participat\$)).tw
 017 ((personal or interpersonal or individual) adj (decision\$ or choice or preference\$ or participat\$)).tw
 018 shared decision making.tw.
 019 decision aid\$.tw.
 020 informed choice.tw.
 021 or/14-20
 016 13 or 21
 017 random\$.tw.
 018 (double adj blind\$).tw.
 019 placebo\$.tw,hw.
 020 or/23-25
 021 22 and 26

WHAT'S NEW

Last assessed as up-to-date: 30 June 2006.

29 April 2009	New citation required and conclusions have changed	A substantially updated version of this review was published on issue 1 2009 of <i>The Cochrane Library</i> . The changes are outlined in the 'History' (date 28 July 2006). The updated review ought to have had a new citation to reflect the new authorship and substantial changes to the review and its conclusions; however because of a technical error this new citation was not given to the updated review. The new citation for this review for issue 3 2009 reflects the updated review contents as actually published from issue 1 2009 onwards.
29 April 2009	New search has been performed	See above, and the 'History' item dated 28 July 2006.
28 April 2009	Amended	Corrected mislabelled table 'Summary of pooled outcomes'.

HISTORY

Protocol first published: Issue 1, 1999

Review first published: Issue 3, 2001

17 July 2008	Amended	Converted to new review format.
28 July 2006	New search has been performed	<p>Changes for the 2006 update (first published on issue 1 2009 of <i>The Cochrane Library</i>):</p> <ul style="list-style-type: none">• Outcomes focus on the new effectiveness criteria of the International Patient Decision Aids Standards (IPDAS) Collaboration• There are now 55 randomised controlled trials evaluating decision aids in the review. Twenty-five new randomised controlled trials have been added for this update. Four trials that were previously included were excluded from this review as the decision support intervention was not available to determine whether it met the inclusion criteria - a requirement for this update in light of the new IPDAS standards. There are an additional 15 trials in progress.• The number of included countries has doubled from the last update. We now have results from 7 countries (AU, CA, China, Finland, Netherlands, US, UK). <p>Findings from the 2006 update (*new to this update):</p> <ul style="list-style-type: none">• * Thirty-eight trials used at least one measure that mapped onto an IPDAS effectiveness criteria. No trials evaluated the extent to which patient decision aids achieve the IPDAS decision process criteria: helped patients to recognize that a decision needs to be made, understand that values affect the

(Continued)

		<p>decision, or discuss values with their practitioner.</p> <ul style="list-style-type: none"> • * Exposure to a decision aid with probabilities resulted in a higher proportion of people with accurate risk perceptions; the effect was stronger when probabilities were measure quantitatively rather than qualitatively. • Compared to usual care, exposure to decision aids improved knowledge, decreased decisional conflict, reduced the proportion of people who were passive in decision making, reduced the proportion who remained undecided, and reduced rates of elective invasive surgery. • Detailed decision aids (compared to simpler decision aids) improved knowledge and reduced the uptake of hormone replacement therapy. • * Compared to usual care, exposure to decision aids reduced PSA screening. • There are too few studies to comment on the effects of decision aids on length of the consult, patient-practitioner communication, persistence with chosen option, costs, and resource use.
21 February 2003	New search has been performed	<p>For the 2002 update (O'Connor 2003b), the following changes were made:</p> <ul style="list-style-type: none"> • There are now 221 decision aids (increased from 87) that have been identified for the inventory with 131 available and up-to-date: many of which are available on the Internet. However few have undergone any form of evaluation for impact on decision making. • There are now 35 randomized controlled trials evaluating decision aids in the review. Eleven new randomized controlled trials have been added for this update including 1 large scale trial that evaluated a suite of 8 decision aids in a number of health services. • There are an additional 6 trials pending publication and 24 trials in progress. • In conjunction with the benefits reported in the earlier reports, there is now evidence that decision aids compared to usual care also help with making actual choices and there is a statistically significant reduction in major elective surgery by a quarter. Detailed compared to simple decision aids also show an improved agreement between values and actual choice. • There continues to be too few studies to comment on the effects of decision aids on persistence with chosen therapy, costs, resource use, or efficacy of dissemination.

CONTRIBUTIONS OF AUTHORS

1999 Review ([O'Connor 1999b](#)):

AO, AR, VF, JT, VE, HLT, MHR, VF, MB, JJ contributed to the design of the protocol, the interpretation of results, and the revision and final approval of the final paper.

AO led the team, JT coordinated the project.

AO, MH-R, AR, VF, and JT pilot tested the data extraction forms.

AR, VF, JT screened studies and extracted data.

AR, JT, and AO analysed results.

2001 Review (O'Connor 2001b):

AO, DS, DR, MHR, HLT, VE, MB, JT, VF, AR contributed to the interpretation of results, and the revision and final approval of the final paper.

AO lead the team and DS coordinated the update.

AO, DR, MHR, HLT, JT, DS, JP screened studies and extracted data.

DS, JP evaluated decision aids using the CREDIBLE criteria.

AO and DS analysed the results.

2002 Review (O'Connor 2003b):

AO, DS, DR, MHR, HLT, VE, MB, JT, VF contributed to the interpretation of results, and the revision and final approval of the paper.

AO lead the team and DS coordinated the update.

DS, JP, VT, JT screened studies and extracted data.

DS, JP, VT, SK evaluated decision aids using the CREDIBLE criteria.

AO and DS analysed the results.

2006 (current) Review:

AO, CB, DS, MB, NC, KE, VE, VF, MHR, SK, HLT, DR, contributed to the interpretation of results, and the revision and final approval of the paper.

AO led the team and CB coordinated the update.

CB, SK, DS, AO, VF screened studies and extracted data.

AO and CB analysed the results.

DECLARATIONS OF INTEREST

Several of the investigators have developed patient decision aids (AO, DS, HL, MH, MB, NC, KE), but none reviewed their own studies. Three investigators (AO, HL, MB) receive support from the not-for-profit Foundation for Informed Medical Decision Making (FIMDM). FIMDM has a licensing agreement with Health Dialog (a commercial firm) that distributes and promotes patient decision aids. NC is co-founder of Strategic Health Decisions, an organization devoted to the development and dissemination of interactive patient decision aids.

SOURCES OF SUPPORT

Internal sources

- Agency for Healthcare Research and Quality, USA.

KE is currently directing patient decision aid development for the John M. Eisenberg Clinical Decisions and Communications Science Center funded by the Agency for Healthcare Research and Quality (HHSA29020050013C) and located at Oregon Health & Science University in Portland, Oregon.

External sources

- Canadian Institutes of Health Research, Canada.

Group Grant in Decision Support Tools for Clinicians and Patients (MGC 42668) provided salary (CB, SK) and material (systematic review software) support.

- Canada Research Chair Program, Canada.

AO holds a Tier 1 Canada Research Chair in Health Care Consumer Decision Support.

INDEX TERMS

Medical Subject Headings (MeSH)

*Decision Support Techniques; *Patient Participation; Patient Education as Topic [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Humans